Clinical trial results:
Safety and Immunogenicity of a 3-Dose Schedule of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers

Summary

EudraCT number	2017-004977-15
Trial protocol	Outside EU/EEA
Global end of trial date	18 February 2022

Results information

Result version number	v1 (current)
This version publication date	10 November 2023
First version publication date	10 November 2023

Trial information

Trial identification

Sponsor protocol code	MET33

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03630705
WHO universal trial number (UTN)	U1111-1183-6409

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	Discovery Drive, Swiftwater, Pennsylvania, 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 June 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To describe the antibody titers to the antigens (meningococcal serogroups A, C, Y, and W) present in Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine or Menveo® measured by serum bactericidal assay using human complement (hSBA), for Groups 1 and 2 when administered concomitantly with routine pediatric vaccines in healthy infants and toddlers in Mexico.
- To describe the antibody titers to the antigens (meningococcal serogroups A, C, Y, and W) present in MenACYW Conjugate vaccine measured by hSBA, for Group 3, when administered concomitantly with routine pediatric vaccines in healthy infants and toddlers in the Russian Federation.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 October 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	Mexico: 300
Country: Number of subjects enrolled	Russian Federation: 225
Worldwide total number of subjects	525
EEA total number of subjects	0

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)	525
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:

Study was conducted from 17 October 2018 to 18 February 2022 at 11 active sites in Mexico and the Russian Federation.

Pre-assignment

Screening details:

A total of 525 subjects were enrolled and randomised in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenACYW Conjugate Vaccine (Mexico)

Arm description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 2, 6, and 12 along with Prevnar 13®, Hexacima® vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6 and measles, mumps, rubella (MMR®II) vaccine at the age of Month 12.

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

Dosage and administration details:

Subjects received MenACYW Conjugate vaccine 0.5 millilitres (mL) intramuscular (IM) injection at the age of Months 2, 6 and 12.

Investigational medicinal product name	Pneumococcal 13-valent Conjugate Vaccine
Investigational medicinal product code	
Other name	Prevnar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Prevnar 13® vaccine 0.5 mL IM injection at the age of Months 2, 4, 6 and 12.

Investigational medicinal product name	Diphtheria, tetanus, pertussis (acellular component), hepatitis B, poliomyelitis (inactivated), and Haemophilus influenzae type b conjugate vaccine
Investigational medicinal product code	
Other name	Hexacima®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Hexacima® 0.5 vaccine mL IM injection at the age of Months 2, 4, 6 and 12.

Investigational medicinal product name	Rotavirus Vaccine
Investigational medicinal product code	
Other name	RotaTeq®

Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details: Subjects received RotaTeq® vaccine 2 mL oral solution at the age of Months 2, 4 and 6.	
Investigational medicinal product name	Measles, Mumps, and Rubella Virus Vaccine
Investigational medicinal product code	
Other name	M-M-R®II
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects received M-M-R®II vaccine 0.5 mL SC injection at the age of Month 12.	
Arm title	Group 2: Menveo® Vaccine (Mexico)
Arm description: Subjects aged 2 months (at the time of enrollment) received Menveo® vaccine at the age of Months 2, 4, 6, and 12 along with Prevnar 13®, Hexacima® vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6, and MMR®II vaccine at the age of Month 12.	
Arm type	Active comparator
Investigational medicinal product name	Meningococcal (Groups A, C, Y and W 135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine
Investigational medicinal product code	
Other name	Menveo®
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Subjects received Menveo® vaccine 0.5 mL IM injection at the age of Months 2, 4, 6, and 12.	
Investigational medicinal product name	Pneumococcal 13-valent Conjugate Vaccine
Investigational medicinal product code	
Other name	Prevnar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Subjects received Prevnar 13® vaccine 0.5 mL IM injection at the age of Months 2, 4, 6 and 12.	
Investigational medicinal product name	Measles, Mumps, and Rubella Virus Vaccine
Investigational medicinal product code	
Other name	M-M-R®II
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects received M-M-R®II vaccine 0.5 mL SC injection at the age of Month 12.	
Investigational medicinal product name	Rotavirus Vaccine
Investigational medicinal product code	
Other name	RotaTeq®
Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details: Subjects received RotaTeq® vaccine 2 mL oral solution at the age of Months 2, 4 and 6.	
Investigational medicinal product name	Diphtheria, tetanus, pertussis (acellular component), hepatitis B, poliomyelitis (inactivated), and Haemophilus influenzae type b conjugate vaccine
Investigational medicinal product code	
Other name	Hexacima®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Hexacima® vaccine 0.5 mL IM injection at the age of Months 2, 4, 6 and 12.

Arm title	Group 3: MenACYW Conjugate Vaccine (Russian Federation)

Arm description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 3, 6, and 12 along with Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.

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

Dosage and administration details:

Subjects received MenACYW Conjugate vaccine 0.5 mL IM injection at the age of Months 3, 6 and 12.

Investigational medicinal product name	Pneumococcal 13-valent Conjugate Vaccine
Investigational medicinal product code	
Other name	Prevnar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Prevnar 13® vaccine 0.5 mL IM injection at the age of Months 2 and 4.5.

Investigational medicinal product name	Measles, Mumps, and Rubella Virus Vaccine
Investigational medicinal product code	
Other name	M-M-R®II
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received M-M-R®II vaccine 0.5 mL SC injection at the age of Month 12.

Investigational medicinal product name	Hepatitis B Vaccine
Investigational medicinal product code	
Other name	ENGERIX-B®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received ENGERIX-B® vaccine 0.5 mL IM injection at the age of Month 6.

Investigational medicinal product name	Diphtheria, Tetanus, Pertussis (Acellular, Component) Poliomyelitis (inactivated) Vaccine, and Haemophilus influenza type b Conjugate Vaccine
Investigational medicinal product code	
Other name	Pentaxim®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Pentaxim® vaccine 0.5 mL IM injection at the age of Months 3, 4.5, and 6.

Arm title	Group 4: Routine Pediatric Vaccines (Russian Federation)

Arm description:	
Subjects aged 2 months (at the time of enrollment) received Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.	
Arm type	Control
Investigational medicinal product name	Pneumococcal 13-valent Conjugate Vaccine
Investigational medicinal product code	
Other name	Prevnar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received Prevnar 13® vaccine 0.5 mL IM injection at the age of Months 2 and 4.5.	
Investigational medicinal product name	Diphtheria, Tetanus, Pertussis (Acellular, Component) Poliomyelitis (inactivated) Vaccine, and Haemophilus influenza type b Conjugate Vaccine
Investigational medicinal product code	
Other name	Pentaxim®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received Pentaxim® vaccine 0.5 mL IM injection at the age of Months 3, 4.5, and 6.	
Investigational medicinal product name	Hepatitis B Vaccine
Investigational medicinal product code	
Other name	ENGERIX-B®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received ENGERIX-B® vaccine 0.5 mL IM injection at the age of Month 6.	
Investigational medicinal product name	Measles, Mumps, and Rubella Virus Vaccine
Investigational medicinal product code	
Other name	M-M-R®II
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Subjects received M-M-R®II vaccine 0.5 mL SC injection at the age of Month 12.	

Number of subjects in period 1	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)
Started	200	100	150
Vaccinated at the Age of 2 Months	200	100	150
Vaccinated at the Age of 3 Months	0 [1]	0 [2]	149
Vaccinated at the Age of 4 Months	195	96	0 [3]
Vaccinated at the Age of 4.5 Months	0 [4]	0 [5]	149
Vaccinated at the Age of 6 Months	194	95	149
Vaccinated at the Age of 12 Months	192	92	148
Completed	190	92	148
Not completed	10	8	2

Withdrawal by Parent/ Guardian	9	6	2
Lost to follow-up	1	2	-

Number of subjects in period 1	Group 4: Routine Pediatric Vaccines (Russian Federation)
Started	75
Vaccinated at the Age of 2 Months	75
Vaccinated at the Age of 3 Months	75
Vaccinated at the Age of 4 Months	0 [6]
Vaccinated at the Age of 4.5 Months	75
Vaccinated at the Age of 6 Months	75
Vaccinated at the Age of 12 Months	75
Completed	75
Not completed	0
Withdrawal by Parent/ Guardian	-
Lost to follow-up	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Group 2 subjects did not receive any vaccination at the age of 3 months.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Group 2 subjects did not receive any vaccination at the age of 3 months.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Group 3 subjects did not receive any vaccination at the age of 4 months.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Group 1 subjects did not receive any vaccination at the age of 4.5 months.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Group 1 subjects did not receive any vaccination at the age of 4.5 months.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Group 3 subjects did not receive any vaccination at the age of 4 months.

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: MenACYW Conjugate Vaccine (Mexico)
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 2, 6, and 12 along with Prevnar 13®, Hexacima® vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6 and measles, mumps, rubella (MMR®II) vaccine at the age of Month 12.	
Reporting group title	Group 2: Menveo® Vaccine (Mexico)
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received Menveo® vaccine at the age of Months 2, 4, 6, and 12 along with Prevnar 13®, Hexacima® vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6, and MMR®II vaccine at the age of Month 12.	
Reporting group title	Group 3: MenACYW Conjugate Vaccine (Russian Federation)
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 3, 6, and 12 along with Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.	
Reporting group title	Group 4: Routine Pediatric Vaccines (Russian Federation)
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.	

Reporting group values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)
Number of subjects	200	100	150
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	2.2	2.3	2.4
standard deviation	± 0.24	± 0.25	± 0.28
Gender categorical Units: Subjects			
Female	100	54	69
Male	100	46	81
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	166	78	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	150
More than one race	0	0	0
Unknown or Not Reported	34	22	0

Reporting group values	Group 4: Routine	Total	

	Pediatric Vaccines (Russian Federation)		
Number of subjects	75	525	
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	2.4		
standard deviation	± 0.29	-	
Gender categorical Units: Subjects			
Female	48	271	
Male	27	254	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	244	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	75	225	
More than one race	0	0	
Unknown or Not Reported	0	56	

End points

End points reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine (Mexico)

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 2, 6, and 12 along with Prevnar 13®, Hexacima® vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6 and measles, mumps, rubella (MMR®II) vaccine at the age of Month 12.

Reporting group title	Group 2: Menveo® Vaccine (Mexico)

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received Menveo® vaccine at the age of Months 2, 4, 6, and 12 along with Prevnar 13®, Hexacima® vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6, and MMR®II vaccine at the age of Month 12.

Reporting group title	Group 3: MenACYW Conjugate Vaccine (Russian Federation)

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 3, 6, and 12 along with Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.

Reporting group title	Group 4: Routine Pediatric Vaccines (Russian Federation)

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.

Subject analysis set title	Group 1: MenACYW Conjugate Vaccine (Mexico)
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 2, 6, and 12 along with Prevnar 13®, Hexacima®, vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6 and MMR®II vaccine at the age of Month 12.

Primary: Percentage of Subjects With Antibody Titers >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate Vaccine: Group 3

End point title	Percentage of Subjects With Antibody Titers >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate Vaccine: Group 3[1][2]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Primary

End point timeframe:

30 days after the last vaccination at the age of 12 months (i.e., at the age of 13 months)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint was descriptive in nature, no statistical analysis was provided.

[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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)			
Subject group type	Reporting group			
Number of subjects analysed	96			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	89.6 (81.7 to 94.9)			
Serogroup C	82.3 (73.2 to 89.3)			
Serogroup Y	80.2 (70.8 to 87.6)			
Serogroup W	80.2 (70.8 to 87.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Antibody Titers Greater Than or Equal to (>=) 1:8 Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2

End point title	Percentage of Subjects With Antibody Titers Greater Than or Equal to (>=) 1:8 Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2[3][4]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by serum bactericidal assay using hSBA assay. Group 3 data were presented separately. Analysis was performed on Per-Protocol Analysis Set 2 (PPAS2) defined for accessing ACYW immune response data for subjects who received at least 1 dose of study vaccine and had valid post-vaccination serology result of 2nd year of life, with no major protocol violations. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Primary

End point timeframe:

30 days after the last vaccination at the age of 12 months (i.e., at the age of 13 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint was descriptive in nature, no statistical analysis was provided.

[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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	60		
Units: percentage of subjects				

number (confidence interval 95%)				
Serogroup A (n = 126, 60)	97.6 (93.2 to 99.5)	95.0 (86.1 to 99.0)		
Serogroup C (n = 126, 60)	99.2 (95.7 to 100)	93.3 (83.8 to 98.2)		
Serogroup Y (n = 125, 60)	100 (97.1 to 100)	100 (94.0 to 100)		
Serogroup W (n = 125, 60)	100 (97.1 to 100)	100 (94.0 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)[5]

End point description:

The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titers >=1:16 for subjects with pre-vaccination hSBA titers less than (<) 1:8 or at least a 4-fold increase in hSBA titers from pre- to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Group 3 data were presented separately. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on Per-Protocol Analysis Set 1 (PPAS1) defined for accessing ACYW immune response data for subjects who received at least 1 dose of study vaccine and had valid post-vaccination serology result of infancy (6 months of age) vaccination stage, with no major protocol deviations. Data for this endpoint was not planned to be collected and analysed

End point type	Secondary

End point timeframe:

30 days after the last vaccination at the age of 6 months of the infant series (i.e., at the age of 7 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	81		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	84.7 (78.5 to 89.6)	58.0 (46.5 to 68.9)		
Serogroup C	100 (97.9 to 100)	86.4 (77.0 to 93.0)		
Serogroup Y	99.4 (96.9 to 100)	92.6 (84.6 to 97.2)		

Serogroup W	98.3 (95.1 to 99.6)	97.5 (91.4 to 99.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate Vaccine: Group 3 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate Vaccine: Group 3 (up to the Infant Age of 6 Months)[6]

End point description:

Antibody titers against meningococcal serogroups A, C, Y, and W were measured by hSBA. The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titers >=1:16 for subjects with pre-vaccination hSBA titers <1:8 or at least a 4-fold increase in hSBA titers from pre- to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the last vaccination at the age of 6 months of the infant series (i.e., at the age of 7 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	70.1 (60.0 to 79.0)			
Serogroup C	94.8 (88.4 to 98.3)			
Serogroup Y	87.6 (79.4 to 93.4)			
Serogroup W	93.8 (87.0 to 97.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration of Pertussis Toxoid (PT) and Filamentous Hemagglutinin (FHA) Antibodies Before Vaccination With Hexacima® Vaccine Administered Along With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Concentration of Pertussis Toxoid (PT) and Filamentous Hemagglutinin (FHA) Antibodies Before Vaccination With Hexacima® Vaccine Administered Along With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)[7]

End point description:

Geometric mean concentration (GMCs) for PT and FHA were measured by electrochemiluminescent (ECL) assay. Concentration was expressed in terms of titers (1/dilution). Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination with Hexacima® vaccine) of the infant series (i.e., at the age of 2 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	60		
Units: titers				
geometric mean (confidence interval 95%)				
PT	5.36 (4.27 to 6.73)	8.34 (6.13 to 11.4)		
FHA	22.0 (17.2 to 28.1)	39.9 (27.8 to 57.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations of Anti-rotavirus Serum Immunoglobulin A (IgA) Antibodies Before and After RotaTeq® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Concentrations of Anti-rotavirus Serum Immunoglobulin A (IgA) Antibodies Before and After RotaTeq® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)[8]

End point description:

GMCs of Anti-rotavirus serum IgA antibodies were assessed using enzyme-linked immunosorbent assay (ELISA). Concentrations were measured in terms of units/millilitre (U/mL). Infant series here denotes

the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination with RotaTeq® vaccine at the age of 2 months) and 30 days after the vaccination with RotaTeq® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	81		
Units: U/mL				
geometric mean (confidence interval 95%)				
Day 0 (at the age of 2 months)	4.24 (3.84 to 4.67)	4.91 (4.00 to 6.01)		
At the age of 7 months	621 (496 to 776)	572 (402 to 815)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration of Antipneumococcal Antibodies After Prevnar 13® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Concentration of Antipneumococcal Antibodies After Prevnar 13® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)[9]

End point description:

GMCs of anti-pneumococcal antibodies was assessed by electrochemiluminscent (ECL) assay. GMCs of Prevnar 13 serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F were reported. Concentration was expressed in terms of titers (1/dilution). Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for the specified categories. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Prevnar 13® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	81		
Units: titers				
geometric mean (confidence interval 95%)				
Serotype 1 (n = 175, 81)	3.28 (2.95 to 3.64)	2.75 (2.34 to 3.24)		
Serotype 3 (n = 175, 81)	0.607 (0.553 to 0.665)	0.498 (0.436 to 0.569)		
Serotype 4 (n = 175, 81)	1.90 (1.73 to 2.08)	1.63 (1.42 to 1.86)		
Serotype 5 (n = 175, 81)	2.26 (2.04 to 2.52)	1.91 (1.65 to 2.21)		
Serotype 6A (n = 175, 81)	4.57 (4.13 to 5.05)	3.76 (3.30 to 4.29)		
Serotype 6B (n = 175, 81)	2.64 (2.30 to 3.03)	1.96 (1.63 to 2.34)		
Serotype 7F (n = 175, 81)	3.97 (3.64 to 4.33)	3.62 (3.21 to 4.08)		
Serotype 9V (n = 175, 81)	2.33 (2.11 to 2.57)	1.99 (1.72 to 2.31)		
Serotype 14 (n = 174, 81)	9.36 (8.47 to 10.3)	9.72 (8.18 to 11.5)		
Serotype 18C (n = 175, 81)	2.24 (2.06 to 2.45)	1.71 (1.49 to 1.97)		
Serotype 19A (n = 175, 81)	2.45 (2.19 to 2.74)	1.95 (1.72 to 2.21)		
Serotype 19F (n = 175, 81)	3.55 (3.20 to 3.94)	2.83 (2.42 to 3.32)		
Serotype 23F (n = 175, 81)	2.05 (1.79 to 2.34)	1.61 (1.38 to 1.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Anti-pneumococcal Antibody Concentrations (>=0.35 mcg/mL and >=1.0 mcg/mL) After Prevnar 13® Vaccine Administered Alone or Along With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With Anti-pneumococcal Antibody Concentrations (>=0.35 mcg/mL and >=1.0 mcg/mL) After Prevnar 13® Vaccine Administered Alone or Along With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)[10]

End point description:

Percentage of subjects with anti-pneumococcal antibody concentrations >=0.35 micrograms per millilitre (mcg/mL) and >=1.0 mcg/mL for Prevnar 13 serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F was reported in this endpoint. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for specified categories. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Prevnar 13® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	81		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 1: >=0.35 mcg/mL (n = 175, 81)	100 (97.9 to 100)	100 (95.5 to 100)		
Serotype 3: >=0.35 mcg/mL (n = 175, 81)	81.7 (75.2 to 87.1)	74.1 (63.1 to 83.2)		
Serotype 4: >=0.35 mcg/mL (n = 175, 81)	99.4 (96.9 to 100)	98.8 (93.3 to 100)		
Serotype 5: >=0.35 mcg/mL (n = 175, 81)	99.4 (96.9 to 100)	100 (95.5 to 100)		
Serotype 6A: >=0.35 mcg/mL (n = 175, 81)	100 (97.9 to 100)	100 (95.5 to 100)		
Serotype 6B: >=0.35 mcg/mL (n = 175, 81)	97.7 (94.3 to 99.4)	98.8 (93.3 to 100)		
Serotype 7F: >=0.35 mcg/mL (n = 175, 81)	100 (97.9 to 100)	100 (95.5 to 100)		
Serotype 9V: >=0.35 mcg/mL (n = 175, 81)	100 (97.9 to 100)	100 (95.5 to 100)		
Serotype 14: >=0.35 mcg/mL (n = 174, 81)	100 (97.9 to 100)	100 (95.5 to 100)		
Serotype 18C: >=0.35 mcg/mL (n = 175, 81)	100 (97.9 to 100)	97.5 (91.4 to 99.7)		
Serotype 19A: >=0.35 mcg/mL (n = 175, 81)	99.4 (96.9 to 100)	100 (95.5 to 100)		
Serotype 19F: >=0.35 mcg/mL (n = 175, 81)	99.4 (96.9 to 100)	98.8 (93.3 to 100)		
Serotype 23F: >=0.35 mcg/mL (n = 175, 81)	96.0 (91.9 to 98.4)	96.3 (89.6 to 99.2)		
Serotype 1: >=1.0 mcg/mL (n = 175, 81)	95.4 (91.2 to 98.0)	95.1 (87.8 to 98.6)		
Serotype 3: >=1.0 mcg/mL (n = 175, 81)	20.0 (14.3 to 26.7)	14.8 (7.9 to 24.4)		
Serotype 4: >=1.0 mcg/mL (n = 175, 81)	84.0 (77.7 to 89.1)	79.0 (68.5 to 87.3)		
Serotype 5: >=1.0 mcg/mL (n = 175, 81)	88.6 (82.9 to 92.9)	81.5 (71.3 to 89.2)		
Serotype 6A: >=1.0 mcg/mL (n = 175, 81)	96.6 (92.7 to 98.7)	96.3 (89.6 to 99.2)		
Serotype 6B: >=1.0 mcg/mL (n = 175, 81)	88.6 (82.9 to 92.9)	81.5 (71.3 to 89.2)		
Serotype 7F: >=1.0 mcg/mL (n = 175, 81)	99.4 (96.9 to 100)	100 (95.5 to 100)		
Serotype 9V: >=1.0 mcg/mL (n = 175, 81)	86.9 (80.9 to 91.5)	85.2 (75.6 to 92.1)		

Serotype 14: >=1.0 mcg/mL (n = 174, 81)	98.9 (95.9 to 99.9)	100 (95.5 to 100)		
Serotype 18C: >=1.0 mcg/mL (n = 175, 81)	90.9 (85.6 to 94.7)	81.5 (71.3 to 89.2)		
Serotype 19A: >=1.0 mcg/mL (n = 175, 81)	86.9 (80.9 to 91.5)	84.0 (74.1 to 91.2)		
Serotype 19F: >=1.0 mcg/mL (n = 175, 81)	97.7 (94.3 to 99.4)	98.8 (93.3 to 100)		
Serotype 23F: >=1.0 mcg/mL (n = 175, 81)	81.1 (74.5 to 86.6)	79.0 (68.5 to 87.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=3-fold and >=4-fold Rise in Anti-rotavirus Serum IgA Antibody Concentrations After RotaTeq® Vaccine Administered Alone or Along With MenACYW Conjugate or Menveo® Vaccine: Groups 1 & 2 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With >=3-fold and >=4-fold Rise in Anti-rotavirus Serum IgA Antibody Concentrations After RotaTeq® Vaccine Administered Alone or Along With MenACYW Conjugate or Menveo® Vaccine: Groups 1 & 2 (up to the Infant Age of 6 Months)[11]

End point description:

Anti-rotavirus IgA antibodies in human serum was measured by ELISA. Fold-rise was calculated as ratio of post-vaccination
titer (i.e., 30 days after 6-months vaccination) to pre-dose titer at age of 2 months (i.e., Day 0). Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

From Day 0 (before the first vaccination with RotaTeq® vaccine at the age of 2 months), 30 days after the vaccination
with RotaTeq® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	81		
Units: percentage of subjects				
number (confidence interval 95%)				
>=3-fold rise	93.8 (89.1 to 96.8)	91.4 (83.0 to 96.5)		
>=4-fold rise	93.8 (89.1 to 96.8)	88.9 (80.0 to 94.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of MMR Antibodies Following Vaccination With M-M-R®II Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2

End point title	Geometric Mean Titers (GMTs) of MMR Antibodies Following Vaccination With M-M-R®II Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2[12]

End point description:

GMTs against anti-measles and anti-rubella antibodies were measured by Bulk Measles immunoglobulin G (IgG) Enzyme Immunoassay (EIA) and anti-mumps antibodies were assessed by ELISA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS2. Here, "number of subjects analysed" signifies subjects with available data for this endpoint and 'n'=subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

30 days after the vaccination with M-M-R®II vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[12] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	60		
Units: titers				
geometric mean (confidence interval 95%)				
Anti-Measles (n = 125, 60)	5256 (4718 to 5855)	5679 (5120 to 6299)		
Anti-Mumps (n - 125, 59)	130 (114 to 149)	109 (83.7 to 142)		
Anti-Rubella (n = 125, 60)	117 (104 to 132)	117 (100 to 136)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration of Anti-pneumococcal Antibodies Following Vaccination With Prevnar 13® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2

End point title	Geometric Mean Concentration of Anti-pneumococcal Antibodies Following Vaccination With Prevnar 13® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2[13]

End point description:

GMCs against Streptococcus pneumoniae polysaccharide (PS) serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F,
and 23F were measured by ECL assay. Concentration was expressed in terms of titers (1/dilution). Analysis was performed on PPAS2. Here, "number of subjects analysed" signifies subjects with available data for this endpoint. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Prevnar13® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[13] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	60		
Units: titers				
geometric mean (confidence interval 95%)				
Serotype 1	2.96 (2.49 to 3.52)	2.74 (2.10 to 3.57)		
Serotype 3	0.504 (0.431 to 0.590)	0.518 (0.398 to 0.674)		
Serotype 4	1.59 (1.32 to 1.93)	1.36 (1.04 to 1.79)		
Serotype 5	2.48 (2.09 to 2.95)	2.18 (1.73 to 2.74)		
Serotype 6A	7.22 (5.92 to 8.80)	5.85 (4.33 to 7.91)		
Serotype 6B	4.89 (3.96 to 6.03)	4.06 (3.03 to 5.46)		
Serotype 7F	3.79 (3.21 to 4.48)	3.91 (3.12 to 4.91)		
Serotype 9V	2.59 (2.14 to 3.14)	2.31 (1.76 to 3.03)		
Serotype 14	7.55 (6.18 to 9.22)	7.47 (5.72 to 9.74)		
Serotype 18C	2.35 (1.97 to 2.82)	1.79 (1.35 to 2.39)		
Serotype 19A	4.13 (3.35 to 5.09)	4.18 (3.16 to 5.53)		
Serotype 19F	4.15 (3.41 to 5.05)	3.84 (2.80 to 5.25)		
Serotype 23F	3.13 (2.52 to 3.90)	2.53 (1.80 to 3.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Anti-pneumococcal Antibody Concentrations (>=0.35 mcg/mL and >=1.0 mcg/mL) Following Vaccination With Prevnar 13® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2

End point title	Percentage of Subjects With Anti-pneumococcal Antibody Concentrations (>=0.35 mcg/mL and >=1.0 mcg/mL) Following Vaccination With Prevnar 13® Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2[14]

End point description:

Percentage of subjects with anti-pneumococcal antibody concentrations >=0.35 mcg/mL and >=1.0 mcg/mL for Prevnar 13 serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F was reported in this endpoint. Analysis was performed on PPAS2. Here, "number of subjects analysed" = subjects with available data for this endpoint. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Prevnar 13® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[14] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	60		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 1: >=0.35 mcg/mL	97.6 (93.1 to 99.5)	98.3 (91.1 to 100)		
Serotype 3: >=0.35 mcg/mL	68.8 (59.9 to 76.8)	66.7 (53.3 to 78.3)		
Serotype 4: >=0.35 mcg/mL	90.4 (83.8 to 94.9)	86.7 (75.4 to 94.1)		
Serotype 5: >=0.35 mcg/mL	95.2 (89.8 to 98.2)	96.7 (88.5 to 99.6)		
Serotype 6A: >=0.35 mcg/mL	98.4 (94.3 to 99.8)	100 (94.0 to 100)		
Serotype 6B: >=0.35 mcg/mL	95.2 (89.8 to 98.2)	93.3 (83.8 to 98.2)		
Serotype 7F: >=0.35 mcg/mL	99.2 (95.6 to 100)	100 (94.0 to 100)		

Serotype 9V: >=0.35 mcg/mL	93.6 (87.8 to 97.2)	90.0 (79.5 to 96.2)		
Serotype 14: >=0.35 mcg/mL	99.2 (95.6 to 100)	98.3 (91.1 to 100)		
Serotype 18C: >=0.35 mcg/mL	93.6 (87.8 to 97.2)	85.0 (73.4 to 92.9)		
Serotype 19A: >=0.35 mcg/mL	96.0 (90.9 to 98.7)	100 (94.0 to 100)		
Serotype 19F: >=0.35 mcg/mL	97.6 (93.1 to 99.5)	91.7 (81.6 to 97.2)		
Serotype 23F: >=0.35 mcg/mL	93.6 (87.8 to 97.2)	90.0 (79.5 to 96.2)		
Serotype 1: >=1.0 mcg/mL	84.0 (76.4 to 89.9)	80.0 (67.7 to 89.2)		
Serotype 3: >=1.0 mcg/mL	20.0 (13.4 to 28.1)	25.0 (14.7 to 37.9)		
Serotype 4: >=1.0 mcg/mL	72.0 (63.3 to 79.7)	65.0 (51.6 to 76.9)		
Serotype 5: >=1.0 mcg/mL	84.8 (77.3 to 90.6)	81.7 (69.6 to 90.5)		
Serotype 6A: >=1.0 mcg/mL	90.4 (83.8 to 94.9)	86.7 (75.4 to 94.1)		
Serotype 6B: >=1.0 mcg/mL	88.8 (81.9 to 93.7)	86.7 (75.4 to 94.1)		
Serotype 7F: >=1.0 mcg/mL	90.4 (83.8 to 94.9)	90.0 (79.5 to 96.2)		
Serotype 9V: >=1.0 mcg/mL	80.8 (72.8 to 87.3)	80.0 (67.7 to 89.2)		
Serotype 14: >=1.0 mcg/mL	94.4 (88.8 to 97.7)	96.7 (88.5 to 99.6)		
Serotype 18C: >=1.0 mcg/mL	82.4 (74.6 to 88.6)	78.3 (65.8 to 87.9)		
Serotype 19A: >=1.0 mcg/mL	84.0 (76.4 to 89.9)	85.0 (73.4 to 92.9)		
Serotype 19F: >=1.0 mcg/mL	84.8 (77.3 to 90.6)	83.3 (71.5 to 91.7)		
Serotype 23F: >=1.0 mcg/mL	82.4 (74.6 to 88.6)	80.0 (67.7 to 89.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Anti-MMR Antibodies (Ab) Concentrations Following Vaccination With MMR Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2

End point title	Percentage of Subjects With Anti-MMR Antibodies (Ab) Concentrations Following Vaccination With MMR Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2[15]

End point description:

Percentage of subjects with anti-measles Ab concentrations >=255 milli-international unit per millilitre (mIU/mL), anti-mumps Ab concentrations: >=10 Ab units/mL, and anti-rubella Ab concentrations >=10 international unit per milliliter (IU/mL) was reported in this endpoint. Analysis was performed on PPAS2. Here, "number of subjects analysed" = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

30 days after the vaccination with M-M-R®II vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[15] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	60		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-Measles (n = 125, 60)	99.2 (95.6 to 100)	100 (94.0 to 100)		
Anti-Mumps (n = 125, 59)	100 (97.1 to 100)	96.6 (88.3 to 99.6)		
Anti-Rubella (n = 125, 60)	100 (97.1 to 100)	100 (94.0 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibodies Concentrations Following Vaccination With Hexacima® (DTaP-IPV-HB-Hib) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 1 and 2

End point title	Percentage of Subjects With Antibodies Concentrations Following Vaccination With Hexacima® (DTaP-IPV-HB-Hib) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 1 and 2[16]

End point description:

Percentage of subjects with anti-diphtheria Ab concentrations: >= 0.1 and 1 IU/mL, and anti-tetanus Ab concentrations: >= 0.1 and 1 IU/mL, anti-poliovirus types 1, 2, and 3 Ab titers >= 8 (1/dilution), anti-hepatitis B surface (HBs) antigen Ab concentrations: >= 10 and >= 100 mIU/mL and anti-polyribosyl-ribitol phosphate (anti-PRP) Ab concentrations: >= 0.15 and 1.0 microgram per millilitre (mcg/mL) were reported in this endpoint. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Groups 3 and 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Hexacima® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[16] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	60		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-Diphtheria: >=0.1	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-Diphtheria: >=1	98.4 (94.3 to 99.8)	93.3 (83.8 to 98.2)		
Anti-Tetanus: >=0.1	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-Tetanus: >=1	100 (97.1 to 100)	98.3 (91.1 to 100)		
Anti-Polio 1: >=8	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-Polio 2: >=8	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-Polio 3: >=8	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-Hepatitis B: >=10	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-Hepatitis B: >=100	100 (97.1 to 100)	100 (94.0 to 100)		
Anti-PRP: >=0.15	100 (97.1 to 100)	98.3 (91.1 to 100)		
Anti-PRP: >=1.0	100 (97.1 to 100)	98.3 (91.1 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibodies Concentrations Following Vaccination With Pentaxim® (DTaP-Hib-IPV) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With Antibodies Concentrations Following Vaccination With Pentaxim® (DTaP-Hib-IPV) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)[17]

End point description:

Percentage of subjects with anti-diphtheria Ab concentrations: >= 0.1 and 1 IU/mL, anti-tetanus Ab concentrations: >= 0.1 and 1 IU/mL, anti-poliovirus types 1, 2, and 3 Ab titers >= 8 (1/dilution), and anti-PRP Ab concentrations: >= 0.15 and 1.0 mcg/mL were reported in this endpoint. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Groups 1 and 2.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Pentaxim® vaccine at the age of 6 months of the infant series (i.e., at the age of Month 7)

Notes:

[17] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	53		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-Diphtheria: >=0.1 (n = 95, 53)	98.9 (94.3 to 100)	92.5 (81.8 to 97.9)		
Anti-Diphtheria: >=1 (n = 95, 53)	80.0 (70.5 to 87.5)	71.7 (57.7 to 83.2)		
Anti-Tetanus: >=0.1 (n = 95, 53)	100 (96.2 to 100)	98.1 (89.9 to 100)		
Anti-Tetanus: >=1 (n = 95, 53)	74.7 (64.8 to 83.1)	54.7 (40.4 to 68.4)		
Anti-Polio 1: >=8 (n = 89, 47)	100 (95.9 to 100)	100 (92.5 to 100)		
Anti-Polio 2: >=8 (n = 89, 47)	100 (95.9 to 100)	100 (92.5 to 100)		
Anti-Polio 3: >=8 (n = 89, 47)	100 (95.9 to 100)	100 (92.5 to 100)		
Anti-PRP: >=0.15 (n = 90, 52)	94.4 (87.5 to 98.2)	90.4 (79.0 to 96.8)		
Anti-PRP: >=1.0 (n = 90, 52)	72.2 (61.8 to 81.1)	57.7 (43.2 to 71.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Response for Pertussis (PT) and FHA Antibodies Following Vaccination With Hexacima® (DTaP-IPV-HB-Hib) Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2

End point title	Percentage of Subjects With Vaccine Response for Pertussis (PT) and FHA Antibodies Following Vaccination With Hexacima® (DTaP-IPV-HB-Hib) Vaccine Administered Alone or Along With the MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2[18]

End point description:

Pertussis and FHA vaccine response was defined as: if the pre-vaccination concentration was >=4*lower limit of quantification (LLOQ), then the post-vaccination concentration was >=pre-vaccination concentration and if the pre-vaccination concentration was <4*LLOQ, then the post-booster vaccination concentration was >= 4*LLOQ. The LLOQ was equal to 2.00 Endotoxin units per millilitre (EU/mL). Analysis was performed on PPAS2. Here, "number of subjects analysed" = subjects with available data for this endpoint.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Hexacima® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[18] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	60		
Units: percentage of subjects				
number (confidence interval 95%)				
PT	92.8 (86.8 to 96.7)	95.0 (86.1 to 99.0)		
FHA	91.2 (84.8 to 95.5)	83.3 (71.5 to 91.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration of PT and FHA Antibodies Before Vaccination With Pentaxim® (DTaP-Hib-IPV) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Concentration of PT and FHA Antibodies Before Vaccination With Pentaxim® (DTaP-Hib-IPV) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)[19]

End point description:

GMCs for PT and FHA were measured by ECL assay. Concentration was expressed in terms of titers (1/dilution). Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, "number of subjects analysed" = subjects with available data for this endpoint. Data for this endpoint was not planned to be collected and analysed for Groups 1 and 2.

End point type	Secondary

End point timeframe:

Day 0 (before first vaccination with Pentaxim® vaccine) of the infant series (i.e., at the age of 2 months)

Notes:

[19] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	53		
Units: titers				
geometric mean (confidence interval 95%)				
PT	2.03 (1.64 to 2.51)	1.75 (1.35 to 2.25)		
FHA	6.99 (5.53 to 8.84)	6.23 (4.36 to 8.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Anti-Hepatitis (HBs) Concentrations Following Vaccination With ENGERIX-B® (Hepatitis B) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With Anti-Hepatitis (HBs) Concentrations Following Vaccination With ENGERIX-B® (Hepatitis B) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)[20]

End point description:

Percentage of subjects with anti-hepatitis B surface (HBs) antigen Ab concentrations: >=10 and >=100 mIU/mL was
presented in this endpoint. Infant series here denotes the vaccines administered at the age of 6 months of subjects . Analysis was performed on PPAS1. Here, "number of subjects analysed" = subjects with available data for this endpoint.

End point type	Secondary

End point timeframe:

30 days after the vaccination with ENGERIX-B® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[20] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	50		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-HBs: >=10	97.7 (91.9 to 99.7)	98.0 (89.4 to 99.9)		

Anti-HBs: >=100	93.1 (85.6 to 97.4)	80.0 (66.3 to 90.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Response for PT and FHA Antibodies Following Vaccination With Pentaxim® (DTaP-Hib-IPV) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With Vaccine Response for PT and FHA Antibodies Following Vaccination With Pentaxim® (DTaP-Hib-IPV) Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4 (up to the Infant Age of 6 Months)[21]

End point description:

Pertussis and FHA vaccine response was defined as: if the pre-vaccination concentration was >=4*LLOQ, then the post-vaccination concentration was >= pre-vaccination concentration and if the pre-vaccination concentration was <4*LLOQ, then the post-booster vaccination concentration was >= 4*LLOQ. The LLOQ was equal to 2.00 EU/mL. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, "number of subjects analysed" = subjects with available data for this endpoint.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Pentaxim® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[21] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	53		
Units: percentage of subjects				
number (confidence interval 95%)				
PT	97.9 (92.5 to 99.7)	90.6 (79.3 to 96.9)		
FHA	97.9 (92.5 to 99.7)	94.3 (84.3 to 98.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations of MMR Antibodies Following Vaccination With MMR Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4

End point title	Geometric Mean Concentrations of MMR Antibodies Following Vaccination With MMR Vaccine Administered Alone or Along With the MenACYW Conjugate Vaccine: Groups 3 and 4[22]

End point description:

GMCs against anti-measles and anti-rubella antibodies were measured by Bulk Measles IgG EIA, and anti-mumps antibodies were assessed by ELISA. Concentrations were expressed in terms of titers (1/dilution). Analysis was performed on PPAS2.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MMR vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[22] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	50		
Units: titers				
geometric mean (confidence interval 95%)				
Anti-Measles	1461 (1128 to 1893)	1233 (800 to 1901)		
Anti-Mumps	50.5 (40.4 to 63.1)	53.5 (40.8 to 70.2)		
Anti-Rubella	47.6 (39.5 to 57.2)	55.2 (42.3 to 72.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Before Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1, 2 and 3 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Before Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1, 2 and 3 (up to the Infant Age of 6 Months)[23]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination with MenACYW Conjugate or Menveo® Vaccine) of the infant series

(i.e., at the age of 2 months)

Notes:

[23] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	81	97	
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A	2.65 (2.39 to 2.93)	2.24 (2.10 to 2.38)	2.88 (2.64 to 3.14)	
Serogroup C	2.16 (2.08 to 2.23)	2.29 (2.13 to 2.47)	2.16 (2.04 to 2.30)	
Serogroup Y	2.62 (2.45 to 2.81)	2.89 (2.51 to 3.33)	2.37 (2.07 to 2.72)	
Serogroup W	3.57 (3.21 to 3.97)	3.15 (2.79 to 3.55)	2.18 (2.04 to 2.32)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Anti-MMR Concentrations Following Vaccination With MMR Vaccine Administered Alone or Along With the MenACYW Vaccine or Routine Pediatric Vaccines: Groups 3 and 4

End point title	Percentage of Subjects With Anti-MMR Concentrations Following Vaccination With MMR Vaccine Administered Alone or Along With the MenACYW Vaccine or Routine Pediatric Vaccines: Groups 3 and 4[24]

End point description:

Percentage of subjects with anti-measles Ab concentrations >=255 mIU/mL, anti-mumps Ab concentrations: >=10 Ab units/mL, and anti-rubella Ab concentrations >=10 IU/mL was reported in this endpoint. Analysis was performed on PPAS2.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MMR vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[24] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	50		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-Measles	93.8 (86.9 to 97.7)	88.0 (75.7 to 95.5)		
Anti-Mumps	89.6 (81.7 to 94.9)	90.0 (78.2 to 96.7)		
Anti-Rubella	95.8 (89.7 to 98.9)	94.0 (83.5 to 98.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Following MenACYW Conjugate Vaccine: Groups 1 and 3 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Following MenACYW Conjugate Vaccine: Groups 1 and 3 (up to the Infant Age of 6 Months)[25]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Group 2 data were presented separately. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[25] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	97		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A	71.7 (56.8 to 90.7)	31.5 (22.2 to 44.9)		

Serogroup C	626 (549 to 714)	267 (196 to 365)		
Serogroup Y	246 (216 to 281)	78.2 (60.3 to 101)		
Serogroup W	340 (294 to 393)	78.7 (61.9 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccines: Groups 1 and 3 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccines: Groups 1 and 3 (up to the Infant Age of 6 Months)[26]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Group 2 data were presented separately. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate vaccine at the age of 6 months of the infant series (i.e., at the age of Month 7)

Notes:

[26] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	97		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >=1:4	96.0 (92.0 to 98.4)	93.8 (87.0 to 97.7)		
Serogroup A: >=1:8	90.9 (85.7 to 94.7)	78.4 (68.8 to 86.1)		
Serogroup C: >=1:4	100 (97.9 to 100)	94.8 (88.4 to 98.3)		
Serogroup C: >=1:8	100 (97.9 to 100)	94.8 (88.4 to 98.3)		
Serogroup Y: >=1:4	99.4 (96.9 to 100)	94.8 (88.4 to 98.3)		
Serogroup Y: >=1:8	99.4 (96.9 to 100)	92.8 (85.7 to 97.0)		
Serogroup W: >=1:4	99.4 (96.9 to 100)	94.8 (88.4 to 98.3)		

Serogroup W: >=1:8	99.4 (96.9 to 100)	94.8 (88.4 to 98.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3 (up to the Infant Age of 6 Months)[27]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days after the 6-months vaccination) to pre-dose titer at 2 months of age (i.e., Day 0). Group 2 data were presented separately. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

From Day 0 (before the first vaccination, at the age of 2 months), 30 days after vaccination with MenACYW Conjugate vaccine at the age of 6 months of infant series (i.e., at the age of 7 months)

Notes:

[27] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	97		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	84.7 (78.5 to 89.6)	70.1 (60.0 to 79.0)		
Serogroup C	100 (97.9 to 100)	94.8 (88.4 to 98.3)		
Serogroup Y	99.4 (96.9 to 100)	87.6 (79.4 to 93.4)		
Serogroup W	98.3 (95.1 to 99.6)	93.8 (87.0 to 97.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With Menveo® Vaccine: Group 2 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With Menveo® Vaccine: Group 2 (up to the Infant Age of 6 Months)[28]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Menveo® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[28] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >=1:4	85.2 (75.6 to 92.1)			
Serogroup A: >=1:8	69.1 (57.9 to 78.9)			
Serogroup C: >=1:4	98.8 (93.3 to 100)			
Serogroup C: >=1:8	97.5 (91.4 to 99.7)			
Serogroup Y: >=1:4	98.8 (93.3 to 100)			
Serogroup Y: >=1:8	97.5 (91.4 to 99.7)			
Serogroup W: >=1:4	100 (95.5 to 100)			
Serogroup W: >=1:8	100 (95.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Following Vaccination With Menveo® Vaccine: Group 2 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Following Vaccination With Menveo® Vaccine: Group 2 (up to the Infant Age of 6 Months)[29]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Menveo® vaccine at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[29] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A	16.7 (12.0 to 23.3)			
Serogroup C	62.4 (47.2 to 82.4)			
Serogroup Y	59.8 (46.9 to 76.1)			
Serogroup W	95.7 (78.4 to 117)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccinations With Menveo® Vaccine: Group 2 (up to the Infant Age of 6 Months)

End point title	Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccinations With Menveo® Vaccine: Group 2 (up to the Infant Age of 6 Months)[30]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days after the vaccination at the age of 6 months) to pre-dose titer at Day 0 (i.e., before the first vaccination, at 2 months of age). Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination, at the age of 2 months), 30 days after vaccination with Menveo®

vaccines at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[30] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	58.0 (46.5 to 68.9)			
Serogroup C	86.4 (77.0 to 93.0)			
Serogroup Y	92.6 (84.6 to 97.2)			
Serogroup W	97.5 (91.4 to 99.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3

End point title	Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3[31]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Group 2 data were presented separately. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[31] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	96		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >=1:4 (n = 126, 96)	98.4 (94.4 to 99.8)	97.9 (92.7 to 99.7)		
Serogroup A: >=1:8 (n = 126, 96)	97.6 (93.2 to 99.5)	89.6 (81.7 to 94.9)		
Serogroup C: >=1:4 (n = 126, 96)	100 (97.1 to 100)	91.7 (84.2 to 96.3)		
Serogroup C: >=1:8 (n = 126, 96)	99.2 (95.7 to 100)	82.3 (73.2 to 89.3)		
Serogroup Y: >=1:4 (n = 125, 96)	100 (97.1 to 100)	83.3 (74.4 to 90.2)		
Serogroup Y: >=1:8 (n = 125, 96)	100 (97.1 to 100)	80.2 (70.8 to 87.6)		
Serogroup W: >=1:4 (n = 125, 96)	100 (97.1 to 100)	85.4 (76.7 to 91.8)		
Serogroup W: >=1:8 (n = 125, 96)	100 (97.1 to 100)	80.2 (70.8 to 87.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Antibodies Following Last Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Antibodies Following Last Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3[32]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Group 2 data were presented separately. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4. Here, n = subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[32] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	96		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n = 126, 96)	145 (114 to 185)	85.4 (54.0 to 135)		
Serogroup C (n = 126,96)	897 (742 to 1086)	214 (130 to 353)		
Serogroup Y (n = 125, 96)	401 (343 to 469)	97.3 (63.4 to 149)		
Serogroup W (n = 125, 96)	639 (542 to 754)	123 (77.1 to 195)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3

End point title	Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With MenACYW Conjugate Vaccine: Groups 1 and 3[33]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days after the vaccination at the age of 6 months) to pre-dose titer at Day 0 (i.e., before the first vaccination, at the age of 2 months). Group 2 data were presented separately. Analysis was performed on PPAS2. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination, at the age of 2 months), 30 days after the vaccination with MenACYW Conjugate vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[33] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	96		
Units: percentage of subjects				

number (confidence interval 95%)				
Serogroup A (n = 126, 96)	96.8 (92.1 to 99.1)	74.0 (64.0 to 82.4)		
Serogroup C (n = 126, 96)	99.2 (95.7 to 100)	81.3 (72.0 to 88.5)		
Serogroup Y (n = 125, 96)	100 (97.1 to 100)	80.2 (70.8 to 87.6)		
Serogroup W (n = 125, 96)	99.2 (95.6 to 100)	79.2 (69.7 to 86.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 3

End point title	Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 3[34]

End point description:

The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titer >=1:16 for subjects with pre-vaccination hSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre- to postvaccination for subjects with pre-vaccination hSBA titers >=1:8. Group 2 data were presented separately. Analysis was performed on PPAS2. Here, 'n' = subjects with available data for specified categories. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[34] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	96		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n = 126, 96)	96.8 (92.1 to 99.1)	74.0 (64.0 to 82.4)		
Serogroup C (n = 126, 96)	99.2 (95.7 to 100)	81.3 (72.0 to 88.5)		
Serogroup Y (n = 125, 96)	100 (97.1 to 100)	80.2 (70.8 to 87.6)		
Serogroup W (n = 125, 96)	99.2 (95.6 to 100)	79.2 (69.7 to 86.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With Menveo® Vaccine: Group 2

End point title	Percentage of Subjects With Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With Menveo® Vaccine: Group 2[35]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Menveo® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[35] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >=1:4	96.7 (88.5 to 99.6)			
Serogroup A: >=1:8	95.0 (86.1 to 99.0)			
Serogroup C: >=1:4	96.7 (88.5 to 99.6)			
Serogroup C: >=1:8	93.3 (83.8 to 98.2)			
Serogroup Y: >=1:4	100 (94.0 to 100)			
Serogroup Y: >=1:8	100 (94.0 to 100)			
Serogroup W: >=1:4	100 (94.0 to 100)			
Serogroup W: >=1:8	100 (94.0 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Antibodies Following Last Vaccination With Menveo® Vaccine: Group 2

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA Antibodies Following Last Vaccination With Menveo® Vaccine: Group 2[36]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Menveo® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[36] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A	65.5 (44.5 to 96.3)			
Serogroup C	77.0 (52.5 to 113)			
Serogroup Y	228 (173 to 301)			
Serogroup W	242 (184 to 318)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With Menveo® Vaccine: Group 2

End point title	Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Vaccination With Menveo® Vaccine: Group 2[37]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days after the vaccination at the age of 12 months) to pre-dose titer at Day 0 (i.e., before first vaccination, at the age of 2 months). Analysis was

performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination, at the age of Month 2), 30 days after the vaccination with Menveo® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[37] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	85.0 (73.4 to 92.9)			
Serogroup C	88.3 (77.4 to 95.2)			
Serogroup Y	96.7 (88.5 to 99.6)			
Serogroup W	100 (94.0 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With Menveo® Vaccine: Group 2

End point title	Percentage of Subjects Achieving Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With Menveo® Vaccine: Group 2[38]

End point description:

The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titer >=1:16 for subjects with pre-vaccination hSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre- to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Analysis was performed on PPAS2. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with Menveo® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[38] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	85.0 (73.4 to 92.9)			
Serogroup C	88.3 (77.4 to 95.2)			
Serogroup Y	96.7 (88.5 to 99.6)			
Serogroup W	100 (94.0 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by Serum Bactericidal Assay Using Baby Rabbit Complement Following MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by Serum Bactericidal Assay Using Baby Rabbit Complement Following MenACYW Conjugate or Menveo® Vaccine: Groups 1 and 2 (up to the Infant Age of 6 Months)[39]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by serum bactericidal assay using rabbit complement (rSBA). Titers were expressed in terms of 1/dilution. Group 3 data were presented separately. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, "number of subjects analysed" = subjects with available data for this endpoint, 'n' = subjects with available data for each specified category and '-99999' and '99999' were used as space fillers which indicated that the 95% confidence interval was not computed as the standard deviation of the sample was 0, since all subjects had the same value. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination, at the age of 2 months), 30 days after the vaccination with MenACYW Conjugate vaccine at the age of 6 months (i.e., at the age of 7 months)

Notes:

[39] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	40		
Units: titers				

geometric mean (confidence interval 95%)				
Serogroup A: Day 0 (n = 90, 40)	2.09 (1.96 to 2.23)	2.03 (1.96 to 2.11)		
Serogroup A: 30 days post-vaccination (n = 89, 40)	387 (293 to 510)	1328 (708 to 2489)		
Serogroup C: Day 0 (n = 90, 40)	2.05 (1.95 to 2.14)	2.38 (1.85 to 3.05)		
Serogroup C: 30 days post-vaccination (n = 89, 40)	1366 (1138 to 1640)	235 (173 to 319)		
Serogroup Y: Day 0 (n = 90, 40)	2.28 (1.93 to 2.69)	2.93 (1.89 to 4.54)		
Serogroup Y: 30 days post-vaccination (n = 89, 40	1056 (872 to 1280)	549 (336 to 897)		
Serogroup W: Day 0 (n = 90, 40)	2.00 (-99999 to 99999)	2.00 (-99999 to 99999)		
Serogroup W: 30 days post-vaccination (n = 89, 40)	2587 (2071 to 3231)	763 (509 to 1143)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by rSBA Following MenACYW Conjugate Vaccine: Group 3 (up to the Infant Age of 6 Months)

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by rSBA Following MenACYW Conjugate Vaccine: Group 3 (up to the Infant Age of 6 Months)[40]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by rSBA. Titers were expressed in terms of 1/dilution. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Here, "number of subjects analysed" = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

Day 0 (before the first vaccination, at the age of Month 2), 30 days after the vaccination of MenACYW Conjugate vaccine at the age of 6 months (i.e., at the age of 7 months)

Notes:

[40] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)			
Subject group type	Reporting group			
Number of subjects analysed	56			
Units: titers				
geometric mean (confidence interval 95%)				

Serogroup A: Day 0 (n = 55)	2.18 (1.83 to 2.61)			
Serogroup A: 30 days post-vaccination (n = 41)	213 (126 to 358)			
Serogroup C: Day 0 (n = 56)	2.02 (1.98 to 2.08)			
Serogroup C: 30 days post-vaccination (n = 45)	460 (286 to 738)			
Serogroup Y: Day 0 (n = 56)	2.15 (1.86 to 2.50)			
Serogroup Y: 30 days post-vaccination (n = 43)	817 (587 to 1138)			
Serogroup W: Day 0 (n = 56)	2.15 (1.93 to 2.40)			
Serogroup W: 30 days post-vaccination (n = 44)	961 (593 to 1558)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by rSBA Following Last Vaccination With MenACYW Conjugate Vaccine or Menveo® Vaccine: Group 3

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by rSBA Following Last Vaccination With MenACYW Conjugate Vaccine or Menveo® Vaccine: Group 3[41]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by rSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS2. Here, "number of subjects analysed" = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[41] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine (Russian Federation)			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A	1234 (864 to 1762)			

Serogroup C	236 (114 to 485)			
Serogroup Y	586 (394 to 871)			
Serogroup W	816 (464 to 1433)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by rSBA Following Last Vaccination With MenACYW Conjugate Vaccine or Menveo® Vaccine: Groups 1 and 2

End point title	Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W Measured by rSBA Following Last Vaccination With MenACYW Conjugate Vaccine or Menveo® Vaccine: Groups 1 and 2[42]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by rSBA. Titers were expressed in terms of 1/dilution. Group 3 data were presented separately. Analysis was performed on PPAS2. Here, "number of subjects analysed" = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination with MenACYW Conjugate or Menveo® vaccine at the age of 12 months (i.e., at the age of 13 months)

Notes:

[42] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	25		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A	1102 (808 to 1502)	5113 (2999 to 8717)		
Serogroup C	2023 (1551 to 2639)	572 (338 to 969)		
Serogroup Y	1156 (913 to 1464)	2288 (1343 to 3900)		
Serogroup W	3135 (2196 to 4474)	1938 (1075 to 3493)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Injection Site Reactions After Any and Each Vaccination

End point title	Number of Subjects With Solicited Injection Site Reactions After Any and Each Vaccination[43]

End point description:

SR: expected AR (sign/symptom) observed & reported under conditions (nature & onset) prelisted (i.e., solicited) in protocol & CRF. Injection site reactions were tenderness, erythema & swelling. Assessment of injection site reactions after MenACYW Conjugate vaccine, Menveo, Prevnar 13, Hexacima, MMR, Pentaxim & ENGERIX-B allowed local reactogenicity assessment & helped to identify injection site reaction per vaccine received. n=0 for Groups (Gps) 2 & 4 of MenACYW vaccine (Vac.) categories; Gps 1, 3 & 4 of Menveo Vac. categories; Gps 3 & 4 of Hexacima Vac. categories; Gps 1 and 2 of Pentaxim and ENGERIX-B Vac. categories signifies that no subjects were evaluable, as specified Vac. were not administered in specified groups. Safety analysis set. n=subjects with data for each specified category & n=0 in categories 2, 3, 4, 4.5, 6 & 12 months(M) signifies that none of subjects received specified category vaccination & thus not available for analysis. AEs reported for each arm per protocol.

End point type	Secondary

End point timeframe:

Within 7 days after any vaccination and each vaccination (i.e., at the age 2 months, 3 months, 4 months, 4.5 months, 6 months and 12 months)

Notes:

[43] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)	Group 1: MenACYW Conjugate Vaccine (Mexico)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	99[44]	150[45]	75[46]	201[47]
Units: subjects				
MenACYW Vac:Tenderness:Post any Vac(n=0,149,0,200)	99999	9	99999	121
MenACYW Vac:Erythema:Post any Vac(n=149,0,200)	99999	11	99999	52
MenACYW Vac:Swelling:Post any Vac(n=0,149,0,200)	99999	6	99999	24
Menveo:Tenderness:Post any Vac(n=99,0,0,0)	60	99999	99999	99999
Menveo:Erythema:Post any Vac(n=99,0,0,0)	13	99999	99999	99999
Menveo:Swelling:Post any Vac(n=99,0,0,0)	9	99999	99999	99999
Prevnar13:Tenderness:Post any Vac(n=99,150,75,200)	57	8	7	125
Prevnar13:Erythema:Post any Vac(n=99,150,75,200)	20	9	4	48
Prevnar13:Swelling:Post any Vac(n=99,150,75,200)	4	5	4	21
Hexacima:Tenderness:Post any Vac(n=99,0,0,200)	56	99999	99999	132
Hexacima:Erythema:Post any Vac(n=99,0,0,200)	20	99999	99999	73

Hexacima:Swelling:Post any Vac(n=99,0,0,200)	7	99999	99999	32
MMR:Tenderness:Post any Vac:(n=91,148,75,191)	24	3	3	69
MMR:Erythema:Post any Vac:(n=91,148,75,191)	27	5	3	66
MMR:Swelling:Post any Vac:(n=91,148,75,191)	6	1	1	14
Pentaxim:Tenderness:Post any Vac(n=0,149,75,0)	99999	7	6	99999
Pentaxim:Erythema:Post any Vac(n=0,149,75,0)	99999	18	4	99999
Pentaxim:Swelling:Post any Vac(n=0,149,75,0)	99999	11	3	99999
ENGERIX-B:Tenderness:Post any Vac(n=0,149,75,0)	99999	5	3	99999
ENGERIX-B:Erythema:Post any Vac(n=0,149,75,0)	99999	8	4	99999
ENGERIX-B:Swelling:Post any Vac(n=0,149,75,0)	99999	5	1	99999
MenACYW:Tenderness:Post age 2M Vac(n=0,0,0,200)	99999	99999	99999	87
MenACYW:Erythema:Post age 2M Vac(n=0,0,0,200)	99999	99999	99999	19
MenACYW:Swelling:Post age 2M Vac(n=0,0,0,200)	99999	99999	99999	9
Menveo:Tenderness:Post age 2M Vac(n=99,0,0,0)	38	99999	99999	99999
Menveo:Erythema:Post age 2M Vac(n=99,0,0,0)	6	99999	99999	99999
Menveo:Swelling:Post age 2M Vac(n=99,0,0,0)	3	99999	99999	99999
Prevnar:Tenderness:Post age2M Vac(n=99,150,75,200)	35	5	5	81
Prevnar:Erythema:Post age2M Vac(n=99,150,75,200)	6	5	2	16
Prevnar:Swelling:Post age2M Vac(n=99,150,75,200)	1	2	2	6
Hexacima:Tenderness:Post age 2M Vac(n=99,0,0,200)	32	99999	99999	82
Hexacima:Erythema:Post age 2M Vac(n=99,0,0,200)	5	99999	99999	21
Hexacima:Swelling:Post age 2M Vac(n=99,0,0,200)	3	99999	99999	9
MenACYW:Tenderness:Post age 3M Vac (n=0,149,0,0)	99999	4	99999	99999
MenACYW:Erythema:Post age 3M Vac (n=0,149,0,0)	99999	6	99999	99999
MenACYW:Swelling:Post age 3M Vac (n=0,148,0,0)	99999	3	99999	99999
Pentaxim:Tenderness:Post age3M Vac(n=0,149,0,75,0)	99999	3	2	99999
Pentaxim:Erythema:Post age3M Vac(n=0,149,0,75,0)	99999	7	2	99999
Pentaxim:Swelling:Post age 3M Vac (n=0,148,0,75,0)	99999	4	2	99999
Menveo:Tenderness:Post age 4M Vac (n=94,0,0,0)	36	99999	99999	99999
Menveo:Erythema:Post age 4M Vac (n=94,0,0,0)	3	99999	99999	99999
Menveo:Swelling:Post age 4M Vac (n=94,0,0,0)	3	99999	99999	99999

Prevnar 13:Tenderness:Post age4M Vac(n=94,0,0,196)	32	99999	99999	71
Prevnar 13:Erythema:Post age4M Vac(n=94,0,0,196)	4	99999	99999	21
Prevnar 13:Swelling:Post age4M Vac(n=94,0,0,196)	2	99999	99999	8
Hexacima:Tenderness:Post age 4M Vac (n=94,0,0,196)	33	99999	99999	77
Hexacima:Erythema:Post age 4M Vac (n=94,0,0,196)	4	99999	99999	26
Hexacima:Swelling:Post age 4M Vac (n=94,0,0,196)	2	99999	99999	15
Prevnar:Tenderness:Post age 4.5M Vac(n=0,149,75,0)	99999	5	4	99999
Prevnar:Erythema:Post age 4.5M Vac(n=0,149,75,0)	99999	5	2	99999
Prevnar:Swelling:Post age 4.5M Vac(n=0,149,75,0)	99999	3	2	99999
Pentaxim:Tenderness:Post age4.5M Vac(n=0,149,75,0)	99999	3	4	99999
Pentaxim:Erythema:Post age4.5M Vac(n=0,149,75,0)	99999	7	2	99999
Pentaxim:Swelling:Post age4.5M Vac(n=0,149,75,0)	99999	4	1	99999
MenACYW:Tenderness:Post age 6M Vac (n=0,149,0,193)	99999	6	99999	75
MenACYW:Erythema:Post age 6M Vac (n=0,149,0,193)	99999	7	99999	20
MenACYW:Swelling:Post age 6M Vac (n=0,149,0,193)	99999	2	99999	7
Menveo:Tenderness:Post age 6M Vac (n=93,0,0,0)	31	99999	99999	99999
Menveo:Erythema:Post age 6M Vac (n=93,0,0,0)	4	99999	99999	99999
Menveo:Swelling:Post age 6M Vac (n=93,0,0,0)	1	99999	99999	99999
Prevnar13:Tenderness:Post age 6M Vac(n=93,0,0,194)	30	99999	99999	75
Prevnar13:Erythema:Post age 6M Vac(n=93,0,0,194)	10	99999	99999	21
Prevnar13:Swelling:Post age 6M Vac(n=93,0,0,194)	1	99999	99999	8
Hexacima:Tenderness:Post age 6M Vac (n=93,0,0,194)	30	99999	99999	73
Hexacima:Erythema:Post age 6M Vac (n=93,0,0,194)	11	99999	99999	32
Hexacima:Swelling:Post age 6M Vac (n=93,0,0,194)	2	99999	99999	11
Pentaxim:Tenderness:Post age 6M Vac (n=0,149,75,0)	99999	5	3	99999
Pentaxim:Erythema:Post age 6M Vac (n=0,149,75,0)	99999	11	3	99999
Pentaxim:Swelling:Post age 6M Vac (n=0,149,75,0)	99999	5	2	99999
ENGERIX-B:Tenderness:Post age 6M Vac(n=0,149,75,0)	99999	5	3	99999
ENGERIX-B:Erythema:Post age 6M Vac(n=0,149,75,0)	99999	8	4	99999
ENGERIX-B:Swelling:Post age 6M Vac(n=0,149,75,0)	99999	5	1	99999
MenACYW:Tenderness:Post age 12M Vac(n=0,148,0,192)	99999	4	99999	77

MenACYW:Erythema:Post age 12M Vac(n=0,148,0,192)	99999	3	99999	21
MenACYW:Swelling:Post age 12M Vac(n=0,148,0,192)	99999	2	99999	11
Menveo:Tenderness:Post age 12M Vac (n=91,0,0,0)	30	99999	99999	99999
Menveo:Erythema:Post age 12M Vac (n=91,0,0,0)	9	99999	99999	99999
Menveo:Swelling:Post age 12M Vac (n=91,0,0,0)	3	99999	99999	99999
Prevnar13:Tenderness:Post age12M Vac(n=69,0,0,144)	21	99999	99999	50
Prevnar13:Erythema:Post age12M Vac(n=69,0,0,144)	10	99999	99999	15
Prevnar13:Swelling:Post age12M Vac(n=69,0,0,144)	2	99999	99999	10
Hexacima:Tenderness:Post age 12M Vac(n=91,0,0,192)	29	99999	99999	79
Hexacima:Erythema:Post age 12M Vac(n=91,0,0,192)	16	99999	99999	37
Hexacima:Swelling:Post age 12M Vac(n=91,0,0,192)	2	99999	99999	16
MMR:Tenderness:Post age 12M Vac (n=91,148,75,191)	24	3	3	69
MMR:Erythema:Post age 12M Vac (n=91,148,75,191)	27	5	3	66
MMR:Swelling:Post age 12M Vac (n=91,148,75,191)	6	1	1	14

Notes:

[44] - 99999=filler, no subjects received specified category vaccination, thus not available for analysis.

[45] - 99999=filler, no subjects received specified category vaccination, thus not available for analysis.

[46] - 99999=filler, no subjects received specified category vaccination, thus not available for analysis.

[47] - 99999=filler, no subjects received specified category vaccination, thus not available for analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Systemic Reactions After Any and Each Vaccination

End point title	Number of Subjects With Solicited Systemic Reactions After Any and Each Vaccination[48]

End point description:

Solicited reaction (SR) was an expected adverse reaction (AR) (sign/symptom) observed and reported under conditions (nature & onset) prelisted (i.e., solicited) in case report form (CRF) and considered as related to product administered. Solicited systemic reactions included fever, vomiting, crying abnormal, drowsiness, appetite lost and irritability. Reported AEs for each arm were presented as pre-specified in study protocol. Safety analysis set: subjects who had received at least 1 dose of the study vaccine and had any safety data available. All subjects had their safety analysed after each dose according to vaccine they actually received at that dose. 'n'=subjects with available data for each specified category, 'n=0' signifies none of subjects received specified category vaccination and thus were not available for analysis. '99999': space filler, signifies that no subjects received specified category vaccination and thus was not available for analysis. Vac=vaccination & M=months.

End point type	Secondary

End point timeframe:

Within 7 days after any vaccination and each vaccination (i.e., at the age of 2 months, 3 months, 4 months, 4.5 months, 6 months and 12 months)

Notes:

[48] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)	Group 1: MenACYW Conjugate Vaccine (Mexico)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	99	150	75	201
Units: subjects				
Fever: Post-any Vac (n=98,149,75,199)	33	11	6	84
Vomiting: Post-any Vac (n=99,150,75,200)	11	6	0	39
Crying abnormal: Post-any Vac (n=99,150,75,200)	50	18	6	117
Drowsiness: Post-any Vac (n=99,150,75,200)	36	33	17	80
Appetite lost: Post-any Vac (n=99,150,75,200)	33	26	11	72
Irritability: Post-any Vac (n=99,150,75,200)	58	32	20	134
Fever: Post Vac at age 2M (n=97,149,75,198)	11	0	0	29
Vomiting: Post Vac at age 2M (n=99,150,75,200)	6	4	0	18
Crying abnormal: Post Vac age 2M (n=99,150,75,200)	29	9	2	72
Drowsiness: Post Vac at age 2M (n=99,150,75,200)	19	15	7	51
Appetite lost: Post Vac at age 2M(n=99,150,75,200)	13	7	2	34
Irritability: Post Vac at age 2M (n=99,150,75,200)	44	13	6	92
Fever: Post Vac at age 3M (n=0,149,75.0)	99999	0	1	99999
Vomiting: Post Vac at age 3M (n=0,149,75,0)	99999	0	0	99999
Crying abnormal: Post Vac at age 3M (n=0,149,75,0)	99999	6	0	99999
Drowsiness: Post Vac at age 3M (n=0,149,75,0)	99999	9	4	99999
Appetite lost: Post Vac at age 3M (n=0,149,75,0)	99999	5	1	99999
Irritability: Post Vac at age 3M (n=0,149,75,0)	99999	5	6	99999
Fever: Post Vac at age 4M (n=93,0,0,195)	17	99999	99999	28
Vomiting: Post Vac at age 4M (n=94,0,0,196)	5	99999	99999	12
Crying abnormal: Post Vac at age 4M (n=94,0,0,196)	30	99999	99999	61
Drowsiness: Post Vac at age 4M (n=94,0,0,196)	21	99999	99999	36
Appetite lost: Post Vac at age 4M (n=94,0,0,196)	12	99999	99999	30

Irritability: Post Vac at age 4M (n=94,0,0,196)	38	99999	99999	74
Fever: Post Vac at age 4.5M (n=0,149,75,0)	99999	9	5	99999
Vomiting: Post Vac at age 4.5M (n=0,149,75,0)	99999	0	0	99999
Crying abnormal:Post Vac at age 4.5M(n=0,149,75,0)	99999	8	3	99999
Drowsiness: Post Vac at age 4.5M (n=0,149,75,0)	99999	13	6	99999
Appetite lost: Post Vac at age 4.5M (n=0,149,75,0)	99999	12	4	99999
Irritability: Post Vac at age 4.5M (n=0,149,75,0)	99999	17	10	99999
Fever: Post Vac at age 6M (n=92,149,75,190)	7	1	0	26
Vomiting: Post Vac at age 6M (n=93,149,75,194)	4	1	0	13
Crying abnormal:Post Vac age 6M (n=93,149,75,194)	20	2	2	60
Drowsiness: Post Vac at age 6M (n=93,149,75,194)	12	12	6	38
Appetite lost: Post Vac at age 6M(n=93,149,75,194)	10	10	6	20
Irritability: Post Vac at age 6M (n=93,149,75,194)	26	10	10	77
Fever: Post Vac at age 12M (n=91,148,75,191)	9	1	0	39
Vomiting: Post Vac at age 12M (n=91,148,75,192)	2	1	0	10
Crying abnormal:Post Vac age 12M (n=91,148,7,1925	21	4	2	60
Drowsiness: Post Vac at age 12M (n=91,148,7,1925	14	6	7	33
Appetite lost:Post Vac at age 12M(n=91,148,75,192)	16	11	3	43
Irritability: Post Vac at age 12M(n=91,148,75,192)	26	13	3	75

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Unsolicited Adverse Events After Any and Each Vaccination

End point title	Number of Subjects With Unsolicited Adverse Events After Any and Each Vaccination[49]

End point description:

An AE was any untoward medical occurrence in a subject or in a clinical investigation subject administered a medicinal product and which did not had any causal relationship with the treatment. An unsolicited AE was an observed AE that did not fulfill the conditions prelisted in the case report book (CRB) in terms of diagnosis and/or onset window post-vaccination. Reported AEs for each arm were presented as pre-specified in the study protocol. Analysis was performed on safety analysis set. Here, 'n' = subjects with available data for each specified category, 'n=0' signifies that none of the subjects received the specified category vaccination and thus were not available for analysis and 99999 = space filler which signifies that no subjects received specified category vaccination and thus not available for analysis. Here, M=months.

End point type	Secondary

End point timeframe:

Within 30 days after any vaccination and each vaccination (i.e., at the age 2 months, 3 months, 4 months, 4.5 months, 6 months and 12 months)

Notes:

[49] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)	Group 1: MenACYW Conjugate Vaccine (Mexico)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	99	150	75	201
Units: subjects				
Post-any vaccination (n=99,150,75,201)	47	15	6	100
Post-vaccination at age of 2M (n=99,150,75,201)	15	5	3	33
Post-vaccination at age of 3M (n=0,149,75,0)	99999	4	1	99999
Post-vaccination at age of 4M (n=95,0,0,196)	15	99999	99999	25
Post-vaccination at age of 4.5M (n=0,149,75,0)	99999	5	0	99999
Post-vaccination at age of 6M (n=94,149,75,195)	23	4	3	45
Post-vaccination at age of 12M (n=91,148,75,193)	17	5	1	43

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events (SAEs) and Adverse Events of Special Interests (AESIs)

End point title	Number of Subjects With Serious Adverse Events (SAEs) and Adverse Events of Special Interests (AESIs)[50]

End point description:

A SAE was any untoward medical occurrence that at any dose resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/ incapacity, was a congenital anomaly/birth defect, or was an important medical event. An AESI was an event for which ongoing monitoring and rapid communication by the Investigator to the Sponsor must be done. Such an event might warrant further investigation in order to characterise and understand it. Depending on the nature of the event, rapid communication by the study Sponsor to other parties (e.g, regulators) might also be warranted. Reported AEs for each arm were presented as pre-specified in the study protocol. Analysis was performed on safety analysis set.

End point type	Secondary

End point timeframe:

From Day 0 (i.e., before first vaccination, at the age of 2 months) up to 30 days post last vaccination at the age of 12 months in each Group (i.e., up to the age of 13 months)

Notes:

[50] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	Group 4: Routine Pediatric Vaccines (Russian Federation)	Group 1: MenACYW Conjugate Vaccine (Mexico)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	99	150	75	201
Units: subjects				
SAE	3	4	2	4
AESI	1	1	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Titers Distribution Less Than (<) 1:4, 1:4 and 1:8 Against Meningococcal Serogroups A, C, Y and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1, 2 and 3 (up to Infant Age of 6 Months)

End point title	Percentage of Subjects With hSBA Titers Distribution Less Than (<) 1:4, 1:4 and 1:8 Against Meningococcal Serogroups A, C, Y and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1, 2 and 3 (up to Infant Age of 6 Months)[51]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Percentage of subjects with hSBA Titers distribution < 1:4, 1:4 and 1:8 is reported in this endpoint. Infant series here denotes the vaccines administered at the age of 6 months of subjects. Analysis was performed on PPAS1. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination at the age of 6 months of the infant series (i.e., at the age of 7 months)

Notes:

[51] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	81	97	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4	4.0	14.8	6.2	

Serogroup A: 1:4	5.1	16.0	15.5	
Serogroup A: 1:8	4.5	11.1	8.2	
Serogroup C: <1:4	0	1.2	5.2	
Serogroup C: 1:4	0	1.2	0	
Serogroup C: 1:8	0	9.9	0	
Serogroup Y: <1:4	0.6	1.2	5.2	
Serogroup Y: 1:4	0	1.2	2.1	
Serogroup Y: 1:8	0	1.2	3.1	
Serogroup W: <1:4	0.6	0	5.2	
Serogroup W: 1:4	0	0	0	
Serogroup W: 1:8	0	1.2	1.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Titers Distribution <1:4, 1:4 and 1:8 Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1, 2 and 3

End point title	Percentage of Subjects With hSBA Titers Distribution <1:4, 1:4 and 1:8 Against Meningococcal Serogroups A, C, Y, and W Following Last Vaccination With MenACYW Conjugate or Menveo® Vaccine: Groups 1, 2 and 3[52]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Percentage of subjects with hSBA Titers distribution < 1:4, 1:4 and 1:8 was reported in this endpoint. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 4.

End point type	Secondary

End point timeframe:

30 days after the vaccination at the age of 12 months (i.e., at the age of 13 months)

Notes:

[52] - 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: Data was reported for the arms applicable for the endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine (Mexico)	Group 2: Menveo® Vaccine (Mexico)	Group 3: MenACYW Conjugate Vaccine (Russian Federation)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	60	96	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n = 126,60,96)	1.6	3.3	2.1	
Serogroup A: 1:4 (n = 126,60,96)	0.8	1.7	8.3	
Serogroup A: 1:8 (n = 126,60,96)	0.8	10.0	15.6	
Serogroup C: <1:4 (n = 126,60,96)	0	3.3	8.3	
Serogroup C: 1:4 (n = 126,60,96)	0.8	3.3	9.4	
Serogroup C: 1:8 (n = 126,60,96)	0	5.0	1.0	

Serogroup Y: <1:4 (n = 125,60,96)	0	0	16.7	
Serogroup Y: 1:4 (n = 125,60,96)	0	0	3.1	
Serogroup Y: 1:8 (n = 125,60,96)	0	0	0	
Serogroup W: <1:4 (n = 125,60,96)	0	0	14.6	
Serogroup W: 1:4 (n = 125,60,96)	0	0	5.2	
Serogroup W: 1:8 (n = 125,60,96)	0	0	1.0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited AEs: Day 0 (before 1st Vac, at 2 months) up to 30 days post any Vac. SRs: within 7 days post any Vac. SAE: Day 0 (before 1st Vac, at 2 months) up to 30 days post last Vac at 12 months in each group (i.e., up to 13 months)

Adverse event reporting additional description:

SR: expected AR (sign/symptom) observed & reported under conditions prelisted (solicited) in protocol & CRF. Unsolicited AE: observed AE that did not fulfill conditions of solicited reactions prelisted in CRF in terms of diagnosis and/or onset window post-vac. Safety population. Fever, crying abnormal & appetite=pyrexia, crying & decrease appetite.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Group 1: MenACYW Conjugate

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 2, 6, and 12 along with Prevnar 13®, Hexacima®, vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6 and MMR®II vaccine at the age of Month 12.

Reporting group title	Group 4: Routine Pediatric Vaccines

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.

Reporting group title	Group 3: MenACYW Conjugate

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at the age of Months 3, 6, and 12 along with Prevnar 13® vaccine at the age of Months 2, and 4.5; Pentaxim® vaccine at the age of Months 3, 4.5, and 6; ENGERIX-B® vaccine at the age of Month 6 and MMR vaccine at the age of Month 12.

Reporting group title	Group 2: Menveo® Vaccine (Mexico)

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received Menveo® vaccine at the age of Months 2, 4, 6, and 12 along with Prevnar 13®, Hexacima®, vaccines at the age of Months 2, 4, 6 and 12; RotaTeq® vaccine at the age of Months 2, 4 and 6 and MMR®II vaccine at the age of Month 12.

Serious adverse events	Group 1: MenACYW Conjugate	Group 4: Routine Pediatric Vaccines	Group 3: MenACYW Conjugate
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 201 (1.99%)	2 / 75 (2.67%)	4 / 150 (2.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head Injury			

subjects affected / exposed	1 / 201 (0.50%)	0 / 75 (0.00%)	0 / 150 (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
Skull Fracture			
subjects affected / exposed	0 / 201 (0.00%)	1 / 75 (1.33%)	0 / 150 (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			
Febrile Convulsion			
subjects affected / exposed	0 / 201 (0.00%)	0 / 75 (0.00%)	0 / 150 (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
Seizure			
subjects affected / exposed	1 / 201 (0.50%)	0 / 75 (0.00%)	0 / 150 (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
Atonic Seizures			
subjects affected / exposed	0 / 201 (0.00%)	0 / 75 (0.00%)	1 / 150 (0.67%)
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			
Proctitis			
subjects affected / exposed	0 / 201 (0.00%)	0 / 75 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Neuroendocrine Cell Hyperplasia Of Infancy			
subjects affected / exposed	0 / 201 (0.00%)	1 / 75 (1.33%)	0 / 150 (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
Infections and infestations			
Covid-19			

subjects affected / exposed	0 / 201 (0.00%)	0 / 75 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis Viral			
subjects affected / exposed	0 / 201 (0.00%)	0 / 75 (0.00%)	1 / 150 (0.67%)
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	0 / 201 (0.00%)	0 / 75 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 201 (1.00%)	1 / 75 (1.33%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 201 (0.00%)	0 / 75 (0.00%)	0 / 150 (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

Serious adverse events	Group 2: Menveo® Vaccine (Mexico)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 99 (3.03%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head Injury			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull Fracture			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	1 / 99 (1.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atonic Seizures			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Proctitis			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Neuroendocrine Cell Hyperplasia Of Infancy			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Covid-19			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis Viral			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			

subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 99 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	2 / 99 (2.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Group 1: MenACYW Conjugate	Group 4: Routine Pediatric Vaccines	Group 3: MenACYW Conjugate
Total subjects affected by non-serious adverse events			
subjects affected / exposed	181 / 201 (90.05%)	34 / 75 (45.33%)	64 / 150 (42.67%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	80 / 201 (39.80%)	17 / 75 (22.67%)	33 / 150 (22.00%)
occurrences (all)	158	30	55
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	106 / 201 (52.74%)	8 / 75 (10.67%)	26 / 150 (17.33%)
occurrences (all)	321	18	64
Crying			
subjects affected / exposed	117 / 201 (58.21%)	6 / 75 (8.00%)	18 / 150 (12.00%)
occurrences (all)	253	9	29
Injection Site Haematoma			
subjects affected / exposed	5 / 201 (2.49%)	0 / 75 (0.00%)	0 / 150 (0.00%)
occurrences (all)	5	0	0
Injection Site Pain			
subjects affected / exposed	142 / 201 (70.65%)	10 / 75 (13.33%)	15 / 150 (10.00%)
occurrences (all)	896	24	43
Pyrexia	Additional description: Pyrexia/Fever events that occurred after 7 days post-		

	vaccination were considered as unsolicited AE.		
subjects affected / exposed	85 / 201 (42.29%)	7 / 75 (9.33%)	12 / 150 (8.00%)
occurrences (all)	126	7	12
Injection Site Swelling			
subjects affected / exposed	38 / 201 (18.91%)	4 / 75 (5.33%)	14 / 150 (9.33%)
occurrences (all)	124	11	31
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	7 / 201 (3.48%)	0 / 75 (0.00%)	0 / 150 (0.00%)
occurrences (all)	7	0	0
Vomiting	Additional description: Vomiting events that occurred after 7 days post-vaccination were considered as unsolicited AE.		
subjects affected / exposed	41 / 201 (20.40%)	0 / 75 (0.00%)	6 / 150 (4.00%)
occurrences (all)	55	0	6
Psychiatric disorders			
Irritability			
subjects affected / exposed	134 / 201 (66.67%)	20 / 75 (26.67%)	32 / 150 (21.33%)
occurrences (all)	318	35	58
Infections and infestations			
Influenza			
subjects affected / exposed	14 / 201 (6.97%)	0 / 75 (0.00%)	0 / 150 (0.00%)
occurrences (all)	16	0	0
Nasopharyngitis			
subjects affected / exposed	31 / 201 (15.42%)	0 / 75 (0.00%)	0 / 150 (0.00%)
occurrences (all)	43	0	0
Pharyngitis			
subjects affected / exposed	29 / 201 (14.43%)	0 / 75 (0.00%)	0 / 150 (0.00%)
occurrences (all)	31	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	72 / 201 (35.82%)	11 / 75 (14.67%)	26 / 150 (17.33%)
occurrences (all)	127	16	45

Non-serious adverse events	Group 2: Menveo® Vaccine (Mexico)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	78 / 99 (78.79%)		
Nervous system disorders			

Somnolence			
subjects affected / exposed	36 / 99 (36.36%)		
occurrences (all)	66		
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	38 / 99 (38.38%)		
occurrences (all)	115		
Crying			
subjects affected / exposed	50 / 99 (50.51%)		
occurrences (all)	100		
Injection Site Haematoma			
subjects affected / exposed	5 / 99 (5.05%)		
occurrences (all)	6		
Injection Site Pain			
subjects affected / exposed	62 / 99 (62.63%)		
occurrences (all)	401		
Pyrexia	Additional description: Pyrexia/Fever events that occurred after 7 days post-vaccination were considered as unsolicited AE.		
subjects affected / exposed	38 / 99 (38.38%)		
occurrences (all)	56		
Injection Site Swelling			
subjects affected / exposed	16 / 99 (16.16%)		
occurrences (all)	31		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 99 (6.06%)		
occurrences (all)	7		
Vomiting	Additional description: Vomiting events that occurred after 7 days post-vaccination were considered as unsolicited AE.		
subjects affected / exposed	14 / 99 (14.14%)		
occurrences (all)	20		
Psychiatric disorders			
Irritability			
subjects affected / exposed	58 / 99 (58.59%)		
occurrences (all)	134		
Infections and infestations			
Influenza			

subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all)	3 / 99 (3.03%) 3 19 / 99 (19.19%) 26 10 / 99 (10.10%) 10		
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	33 / 99 (33.33%) 51		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 October 2019	The following changes done: - Revised to stipulate that original protocol was amended. - Philippine sites were removed to reduce risk of delay in Mexico and the Russian Federation. All information related to the Philippines had been removed. - Updated study Responsible Medical Officer (RMO) and study Regional Trial Manager (RTM) in Mexico. - Updated protocol history and current (anticipated) study dates. - Modified objective: Descriptive study design was changed for Groups 3 and 4 in the Russian Federation, to demonstrate that safety profile & immunogenicity of MenACYW conjugate vaccine was similar when given concomitantly with routine pediatric vaccines (MMR, Pentaxim, and ENGERIX-B) to healthy infants & toddlers. - Number of planned subjects, planned sample size, revised to reflect removal of Philippines sites. - Sample size and power calculations were modified to reflect the decrease in overall number of planned subjects, due to removal of the Philippines sites. - Removal of Menveo® from the Russian Federation. - Removal of varicella from Mexico. Revised to reflect inclusion of Prevnar 13 (PCV13) vaccine to be administered in Groups 1 and 2 (Mexico) at 12 months of age. - Footnote added to reflect that VARIVAX® vaccine, administered at/after 12 months of age, would be provided by Sanofi Pasteur as a benefit vaccine in Mexico. - Descriptions of blood sampling schedules, by treatment group, were revised to specify study days of sample collection in relation to vaccine doses/study visits. - Revised to align with current Sanofi Pasteur safety procedures. - Modified primary, secondary, safety and observational objectives and endpoints and added immunogenicity objectives based on removal of Menveo® as active comparator vaccine in Group 4 in the Russian Federation. - Revised to clarify laboratory(ies) for assay processing. - Updated varicella vaccine should not be administered at same time as Hexacima vaccine. - Revised inclusion criteria.

10 March 2020	The following changes were done: - Revised to reflect the protocol amendment number. - Health Authority File Numbers for Mexico and the Russian Federation were included. - Coordinating Investigators for Mexico and the Russian Federation were included. - Contact details for the RMO responsible for the Russian Federation was updated. - Updated version number and date. Updated the table on "History of Protocol Versions" to include V2.0. - Updated to reflect current (anticipated) study dates. - Updated trial design and methodology in synopsis. - Screening criteria for the Russian Federation was updated to include the possibility of using results of complete blood count and biochemistry laboratory tests and urine chemistry tests performed within 7 days of study start (Visit 0). - Updated table of study procedures. - Team Member Update to reflect the RMOs responsible for each country. - Updated study design and study plan. - The total blood and urine volumes were indicated in the tables. - Updated the total blood and urine volumes to be obtained at each visit in the study. - Updated blood samples detail. - A possibility of using results of urine laboratory tests performed 7 days before study start (Visit 0) was included. - The priority for antigen testing was included for Mexico and the Russian Federation. - Updated biological safety assessment methods for sites in the Russian Federation only. - The complete blood count and Blood Chemistry were updated in an order based on the Investigator's medical judgement and available blood volume. - Team Member Update to reflect the RMOs responsible for each country. - Text was added to align it with the protocol template.
23 June 2021	The fallowing changes were done: - Updated to reflect the Coordinating Investigator responsible for the study. - Updated to reflect the Principal Investigators responsible for the study. - Team Member Update to reflect the Responsible Medical Officer, the Global Safety Officer and Clinical Trial Manager responsible for the study. - Updated version number and date. - Updated the table to include the previous version of the protocol. - Updated the study period. - Modified text to improve clarity. - The immunogenicity objectives initially listed as observational objectives had been placed under secondary objectives. The language had not been changed. - Added latest information on vaccine approval. - Updated to reflect current (anticipated) study dates. - Minor changes to improve the clarity. - Updated to align with the new department name. - A new section on a conditional sensitivity analysis was added to document the impact of Coronavirus disease (COVID-19) pandemic situation on the study conduct. - Updated text to include coronavirus vaccination. - Potential deviations due to pandemic environment such as out of window vaccinations or blood draws could require an increase of sample size.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported