Clinical trial results:
Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine Administered Concomitantly With Other Pediatric Vaccines in Healthy Toddlers

Summary

EudraCT number	2018-001472-38
Trial protocol	Outside EU/EEA
Global end of trial date	19 July 2018

Results information

Result version number	v1
This version publication date	08 August 2019
First version publication date	08 August 2019

Trial information

Trial identification

Sponsor protocol code	MET57

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03205371
WHO universal trial number (UTN)	U1111-1161-2787

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001930-PIP01-16
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the immunogenicity profile of MenACYW conjugate vaccine administered alone or concomitantly with licensed pediatric vaccine(s) ((measles-mumps-rubella vaccine [MMR] +Varicella, diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis, and Haemophilus influenzae type-b Conjugate vaccine [DTaP-IPV-HB-Hib], or pneumococcal Conjugate vaccine [PCV13]).

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 were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 November 2016
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: 400
Country: Number of subjects enrolled	Russian Federation: 400
Country: Number of subjects enrolled	Korea, Republic of: 213
Country: Number of subjects enrolled	Thailand: 170
Worldwide total number of subjects	1183
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)	1183
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 subjects were enrolled in South Korea, Mexico, the Russian Federation, and Thailand from 07 November 2016 to 13 June 2018.

Pre-assignment

Screening details:

A total of 1183 subjects were enrolled and randomized 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	South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine, measles-mumps-rubella vaccine (MMR) vaccine, and varicella vaccine on Day 0.

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

Dosage and administration details:

0.5 milliliter (mL), intramuscular, single dose on Day 0.

Investigational medicinal product name	Measles, Mumps, and Rubella 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:

0.5 mL, subcutaneous, single dose on Day 0.

Investigational medicinal product name	Varicella Vaccine
Investigational medicinal product code	
Other name	VARIVAX
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

Arm title	South Korea (Group 2): MenACYW Conjugate Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

Arm type	Experimental

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	South Korea (Group 3): MMR + Varicella Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.

Arm type	Active comparator
Investigational medicinal product name	Measles, Mumps, and Rubella 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:

0.5 mL, subcutaneous, single dose on Day 0.

Investigational medicinal product name	Varicella Vaccine
Investigational medicinal product code	
Other name	VARIVAX
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

Arm title	Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine , MMR vaccine, and Varicella vaccine on Day 0.

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Investigational medicinal product name	Measles, Mumps, and Rubella 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:

0.5 mL, subcutaneous, single dose on Day 0.

Investigational medicinal product name	Varicella Vaccine
Investigational medicinal product code	
Other name	VARIVAX
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

Arm title	Thailand (Group 11): MenACYW Conjugate Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Thailand (Group 12): MMR + Varicella Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.

Arm type	Experimental
Investigational medicinal product name	Measles, Mumps, and Rubella 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:

0.5 mL, subcutaneous, single dose on Day 0.

Investigational medicinal product name	Varicella Vaccine
Investigational medicinal product code	
Other name	VARIVAX
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

Arm title	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type-b (DTaP-IPV-HB-Hib) vaccine on Day 0.

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Investigational medicinal product name	DTaP-IPV-HB-Hib: Diphtheria, tetanus, pertussis (acellular), hepatitis B, poliomyelitis (inactivated), and Haemophilus influenzae type b conjugate vaccine
Investigational medicinal product code	
Other name	Hexaxim ®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Mexico (Group 5): MenACYW Conjugate Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0.

Arm type	Active comparator
Investigational medicinal product name	DTaP-IPV-HB-Hib: Diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis, and Haemophilus influenzae type-b conjugate vaccine
Investigational medicinal product code	
Other name	Hexaxim ®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate and pneumococcal Conjugate vaccine (PCV13) on Day 0.

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Investigational medicinal product name	PCV13: Pneumococcal 13-valent Conjugate Vaccine
Investigational medicinal product code	
Other name	Prevenar 13
Pharmaceutical forms	Suspension for injection

Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Russian Federation (Group 8): MenACYW Conjugate Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

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

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Arm title	Russian Federation (Group 9): PCV13 Vaccine

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13 vaccine on Day 0.

Arm type	Active comparator
Investigational medicinal product name	PCV13: Pneumococcal 13-valent Conjugate Vaccine
Investigational medicinal product code	
Other name	Prevenar 13
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

Number of subjects in period 1	South Korea(Group1): MenACYW Conjugate +MMR+ Varicella	South Korea (Group 2): MenACYW Conjugate Vaccine	South Korea (Group 3): MMR + Varicella Vaccine
Started	107	53	53
Safety Analysis Set	103	52	53
Per-protocol Analysis Set	92 [1]	45 [2]	50 [3]
Completed	103	52	53
Not completed	4	1	0
Consent withdrawn by subject	4	1	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Thailand (Group 10): MenACYW Conjugate	Thailand (Group 11): MenACYW Conjugate Vaccine	Thailand (Group 12): MMR + Varicella Vaccine

	+MMR+Varicella Vaccine		
Started	86	42	42
Safety Analysis Set	86	42	42
Per-protocol Analysis Set	85 [4]	42	42
Completed	86	42	42
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Started	200	100	100
Safety Analysis Set	200	100	100
Per-protocol Analysis Set	155 [5]	79 [6]	68 [7]
Completed	190	97	95
Not completed	10	3	5
Consent withdrawn by subject	4	-	2
Adverse event, non-fatal	-	1	-
Lost to follow-up	5	2	3
Protocol deviation	1	-	-

Number of subjects in period 1	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine	Russian Federation (Group 9): PCV13 Vaccine
Started	200	100	100
Safety Analysis Set	200	100	99
Per-protocol Analysis Set	196 [8]	96 [9]	92 [10]
Completed	200	100	99
Not completed	0	0	1
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[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: Per-Protocol analysis set included all subjects who received at least 1 dose of study

vaccine, and had no protocol deviations.

[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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[7] - 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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[8] - 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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[9] - 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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[10] - 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: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

Reporting groups	
Reporting group title	South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine, measles-mumps-rubella vaccine (MMR) vaccine, and varicella vaccine on Day 0.	
Reporting group title	South Korea (Group 2): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	South Korea (Group 3): MMR + Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.	
Reporting group title	Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine , MMR vaccine, and Varicella vaccine on Day 0.	
Reporting group title	Thailand (Group 11): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Thailand (Group 12): MMR + Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.	
Reporting group title	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type-b (DTaP-IPV-HB-Hib) vaccine on Day 0.	
Reporting group title	Mexico (Group 5): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0.	
Reporting group title	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate and pneumococcal Conjugate vaccine (PCV13) on Day 0.	
Reporting group title	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Russian Federation (Group 9): PCV13 Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13	

Reporting group values	South Korea(Group1): MenACYW Conjugate +MMR+ Varicella	South Korea (Group 2): MenACYW Conjugate Vaccine	South Korea (Group 3): MMR + Varicella Vaccine
Number of subjects	107	53	53
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	12.7	12.7	12.3
standard deviation	± 1.58	± 1.50	± 0.96
Gender categorical Units: Subjects			
Female	49	18	29
Male	58	35	24
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	106	53	53
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Unknown or Not Reported	107	53	53

Reporting group values	Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine	Thailand (Group 11): MenACYW Conjugate Vaccine	Thailand (Group 12): MMR + Varicella Vaccine
Number of subjects	86	42	42
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	12.4	12.4	12.8
standard deviation	± 0.90	± 0.88	± 1.76
Gender categorical Units: Subjects			
Female	47	23	23
Male	39	19	19

Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	86	42	42
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	86	42	42
Unknown or Not Reported	0	0	0

Reporting group values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Number of subjects	200	100	100
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	16.4	16.8	16.8
standard deviation	± 2.73	± 2.83	± 2.99
Gender categorical Units: Subjects			
Female	93	46	48
Male	107	54	52
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	200	100	99
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	200	100	98
Not Hispanic or Latino	0	0	2
Unknown or Not Reported	0	0	0

Reporting group values	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine	Russian Federation (Group 9): PCV13 Vaccine
Number of subjects	200	100	100

Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	16.5	16.0	16.3
standard deviation	± 2.36	± 3.10	± 2.26
Gender categorical Units: Subjects			
Female	78	51	45
Male	122	49	55
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	1	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	198	99	96
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	0	1
Not Hispanic or Latino	196	100	99
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	1183		
Age categorical Units: Subjects			

Age continuous Units: months arithmetic mean standard deviation	-		
Gender categorical Units: Subjects			
Female	550		
Male	633		
Race Units: Subjects			
American Indian or Alaska Native	0		
Asian	179		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	792		
More than one race	0		
Unknown or Not Reported	212		
Ethnicity Units: Subjects			

Hispanic or Latino	403		
Not Hispanic or Latino	567		
Unknown or Not Reported	213		

End points

End points reporting groups

Reporting group title	South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine, measles-mumps-rubella vaccine (MMR) vaccine, and varicella vaccine on Day 0.	
Reporting group title	South Korea (Group 2): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	South Korea (Group 3): MMR + Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.	
Reporting group title	Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine , MMR vaccine, and Varicella vaccine on Day 0.	
Reporting group title	Thailand (Group 11): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Thailand (Group 12): MMR + Varicella Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.	
Reporting group title	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type-b (DTaP-IPV-HB-Hib) vaccine on Day 0.	
Reporting group title	Mexico (Group 5): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0.	
Reporting group title	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate and pneumococcal Conjugate vaccine (PCV13) on Day 0.	
Reporting group title	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Russian Federation (Group 9): PCV13 Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13	

vaccine on Day 0.

Subject analysis set title	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+Varicella Vaccine
Subject analysis set type	Per protocol

Subject analysis set description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW Conjugate vaccine, MMR vaccine, and varicella vaccine on Day 0.

Subject analysis set title	Groups 2 and 11: MenACYW Conjugate Vaccine
Subject analysis set type	Per protocol

Subject analysis set description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW conjugate vaccine on Day 0.

Subject analysis set title	Groups 3 and 12: MMR + Varicella Vaccine
Subject analysis set type	Per protocol

Subject analysis set description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MMR vaccine and varicella vaccine on Day 0.

Primary: Geometric Mean Titers of MenACYW Antibodies Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

End point title	Geometric Mean Titers of MenACYW Antibodies Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11[1][2]

End point description:

Antibody titers of MenACYW were measured by serum bactericidal assay using human complement (hSBA) assay. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS which included subjects who received at least one dose of the study vaccine(s), had a valid post-vaccination blood sample result and no protocol deviations. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

End point type	Primary

End point timeframe:

Day 0 and Day 30 post-vaccination

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 is descriptive in nature, no statistical analysis is 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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	79	196	96
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
Serogroup A: Day 0	5.35 (4.82 to 5.94)	5.49 (4.66 to 6.45)	5.99 (5.30 to 6.76)	8.54 (6.47 to 11.3)
Serogroup A: Day 30	31.4 (25.9 to 38.1)	37.8 (28.5 to 50.2)	24.6 (20.2 to 30.1)	49.0 (36.8 to 65.3)

Serogroup C: Day 0	2.21 (2.11 to 2.31)	2.16 (2.00 to 2.34)	2.77 (2.43 to 3.16)	3.69 (2.84 to 4.81)
Serogroup C: Day 30	749 (633 to 886)	666 (538 to 825)	205 (156 to 269)	309 (218 to 437)
Serogroup Y: Day 0	2.63 (2.37 to 2.92)	2.94 (2.45 to 3.53)	2.90 (2.56 to 3.28)	3.49 (2.68 to 4.53)
Serogroup Y: Day 30	79.7 (65.7 to 96.6)	90.9 (66.8 to 124)	139 (111 to 173)	172 (130 to 229)
Serogroup W: Day 0	2.41 (2.22 to 2.62)	2.16 (2.04 to 2.30)	2.93 (2.54 to 3.38)	3.62 (2.73 to 4.79)
Serogroup W: Day 30	40.0 (32.5 to 49.3)	50.9 (37.2 to 69.8)	57.4 (47.9 to 68.6)	57.0 (44.3 to 73.5)

End point values	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+ Varicella Vaccine	Groups 2 and 11: MenACYW Conjugate Vaccine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	177	87		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
Serogroup A: Day 0	5.20 (4.56 to 5.93)	6.10 (5.00 to 7.44)		
Serogroup A: Day 30	43.9 (37.4 to 51.6)	30.0 (23.1 to 39.0)		
Serogroup C: Day 0	2.37 (2.11 to 2.65)	2.58 (2.15 to 3.10)		
Serogroup C: Day 30	876 (725 to 1057)	600 (456 to 790)		
Serogroup Y: Day 0	3.14 (2.78 to 3.54)	3.12 (2.58 to 3.78)		
Serogroup Y: Day 30	88.9 (75.1 to 105)	60.0 (47.3 to 76.3)		
Serogroup W: Day 0	2.15 (2.00 to 2.30)	2.31 (2.02 to 2.64)		
Serogroup W: Day 30	46.8 (39.1 to 56.0)	35.5 (27.6 to 45.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Antibody Titers >=1:4 and 1:8 Against Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

End point title	Percentage of Subjects With Antibody Titers >=1:4 and 1:8 Against Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11[3][4]

End point description:

Antibody titers of Men A, C, Y, and W were measured by hSBA assay. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

End point type	Primary

End point timeframe:

Day 0 and Day 30 post-vaccination

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 is descriptive in nature, no statistical analysis is 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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	79	196	96
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: Day 0 (>=1:4)	82.6 (75.7 to 88.2)	82.3 (72.1 to 90.0)	82.1 (76.1 to 87.2)	85.4 (76.7 to 91.8)
Serogroup A: Day 0 (>=1:8)	45.8 (37.8 to 54.0)	46.8 (35.5 to 58.4)	49.0 (41.8 to 56.2)	54.2 (43.7 to 64.4)
Serogroup A: Day 30 (>=1:4)	98.1 (94.4 to 99.6)	97.5 (91.2 to 99.7)	94.9 (90.8 to 97.5)	97.9 (92.7 to 99.7)
Serogroup A: Day 30 (>=1:8)	92.9 (87.7 to 96.4)	89.9 (81.0 to 95.5)	83.7 (77.7 to 88.6)	90.6 (82.9 to 95.6)
Serogroup C: Day 0 (>=1:4)	12.3 (7.5 to 18.5)	7.6 (2.8 to 15.8)	19.9 (14.5 to 26.2)	36.5 (26.9 to 46.9)
Serogroup C: Day 0 (>=1:8)	1.9 (0.4 to 5.6)	1.3 (0.0 to 6.9)	8.7 (5.1 to 13.5)	17.7 (10.7 to 26.8)
Serogroup C: Day 30 (>=1:4)	100.0 (97.6 to 100.0)	100.0 (95.4 to 100.0)	98.5 (95.6 to 99.7)	99.0 (94.3 to 100.0)
Serogroup C: Day 30 (>=1:8)	100.0 (97.6 to 100.0)	100.0 (95.4 to 100.0)	93.9 (89.5 to 96.8)	99.0 (94.3 to 100.0)
Serogroup Y: Day 0 (>=1:4)	19.4 (13.5 to 26.5)	25.3 (16.2 to 36.4)	21.9 (16.4 to 28.4)	32.3 (23.1 to 42.6)
Serogroup Y: Day 0 (>=1:8)	11.0 (6.5 to 17.0)	12.7 (6.2 to 22.0)	14.3 (9.7 to 20.0)	15.6 (9.0 to 24.5)
Serogroup Y: Day 30 (>=1:4)	98.7 (95.4 to 99.8)	100.0 (95.4 to 100.0)	98.5 (95.6 to 99.7)	99.0 (94.3 to 100.0)
Serogroup Y: Day 30 (>=1:8)	98.7 (95.4 to 99.8)	98.7 (93.1 to 100.0)	97.4 (94.1 to 99.2)	97.9 (92.7 to 99.7)
Serogroup W: Day 0 (>=1:4)	14.8 (9.6 to 21.4)	8.9 (3.6 to 17.4)	16.8 (11.9 to 22.8)	26.0 (17.6 to 36.0)
Serogroup W: Day 0 (>=1:8)	7.7 (4.1 to 13.1)	2.5 (0.3 to 8.8)	12.8 (8.4 to 18.3)	20.8 (13.2 to 30.3)
Serogroup W: Day 30 (>=1:4)	97.4 (93.5 to 99.3)	96.2 (89.3 to 99.2)	95.9 (92.1 to 98.2)	96.9 (91.1 to 99.4)
Serogroup W: Day 30 (>=1:8)	90.3 (84.5 to 94.5)	92.4 (84.2 to 97.2)	94.4 (90.2 to 97.2)	95.8 (89.7 to 98.9)

End point values	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+Varicella Vaccine	Groups 2 and 11: MenACYW Conjugate Vaccine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	177	87		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: Day 0 (>=1:4)	75.1 (68.1 to 81.3)	82.8 (73.2 to 90.0)		
Serogroup A: Day 0 (>=1:8)	37.9 (30.7 to 45.4)	44.8 (34.1 to 55.9)		
Serogroup A: Day 30 (>=1:4)	98.9 (96.0 to 99.9)	95.4 (88.6 to 98.7)		
Serogroup A: Day 30 (>=1:8)	97.7 (94.3 to 99.4)	92.0 (84.1 to 96.7)		
Serogroup C: Day 0 (>=1:4)	9.6 (5.7 to 14.9)	16.1 (9.1 to 25.5)		
Serogroup C: Day 0 (>=1:8)	4.0 (1.6 to 8.0)	6.9 (2.6 to 14.4)		
Serogroup C: Day 30 (>=1:4)	100.0 (97.9 to 100.0)	100.0 (95.8 to 100.0)		
Serogroup C: Day 30 (>=1:8)	100.0 (97.9 to 100.0)	100.0 (95.8 to 100.0)		
Serogroup Y: Day 0 (>=1:4)	32.2 (25.4 to 39.6)	28.7 (19.5 to 39.4)		
Serogroup Y: Day 0 (>=1:8)	18.6 (13.2 to 25.2)	17.2 (10.0 to 26.8)		
Serogroup Y: Day 30 (>=1:4)	99.4 (96.9 to 100.0)	96.6 (90.3 to 99.3)		
Serogroup Y: Day 30 (>=1:8)	99.4 (96.9 to 100.0)	95.4 (88.6 to 98.7)		
Serogroup W: Day 0 (>=1:4)	5.1 (2.4 to 9.4)	11.5 (5.7 to 20.1)		
Serogroup W: Day 0 (>=1:8)	1.1 (0.1 to 4.0)	2.3 (0.3 to 8.1)		
Serogroup W: Day 30 (>=1:4)	98.9 (96.0 to 99.9)	96.6 (90.3 to 99.3)		
Serogroup W: Day 30 (>=1:8)	96.0 (92.0 to 98.4)	92.0 (84.1 to 96.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

End point title	Percentage of Subjects With >=4-Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following

	Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11[5][6]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

End point type	Primary

End point timeframe:

Day 0 up to Day 30 post-vaccination

Notes:

[5] - 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 is descriptive in nature, no statistical analysis is provided.

[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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	79	196	96
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	69.0 (61.1 to 76.2)	70.9 (59.6 to 80.6)	58.2 (50.9 to 65.2)	72.9 (62.9 to 81.5)
Serogroup C	100.0 (97.6 to 100.0)	98.7 (93.1 to 100.0)	92.3 (87.7 to 95.7)	91.7 (84.2 to 96.3)
Serogroup Y	96.8 (92.6 to 98.9)	94.9 (87.5 to 98.6)	94.4 (90.2 to 97.2)	93.8 (86.9 to 97.7)
Serogroup W	86.5 (80.0 to 91.4)	92.4 (84.2 to 97.2)	88.8 (83.5 to 92.8)	90.6 (82.9 to 95.6)

End point values	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+ Varicella Vaccine	Groups 2 and 11: MenACYW Conjugate Vaccine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	177	87		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	82.5 (76.1 to 87.8)	64.4 (53.4 to 74.4)		
Serogroup C	98.3 (95.1 to 99.6)	98.9 (93.8 to 100.0)		
Serogroup Y	95.5 (91.3 to 98.0)	89.7 (81.3 to 95.2)		
Serogroup W	94.9 (90.6 to 97.6)	89.7 (81.3 to 95.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Vaccine Seroresponse for Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

End point title	Percentage of Subjects Achieving hSBA Vaccine Seroresponse for Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11[7][8]

End point description:

The hSBA vaccine seroresponse for serogroups A, C, Y, and W was defined as post-vaccination hSBA titers >=1:16 for subjects with pre-vaccination titers <1:8 or at least a 4-fold increase in post-vaccination hSBA titers from pre- to post-vaccination, for subjects with pre-vaccination titers >=1:8. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

End point type	Primary

End point timeframe:

Day 30 post-vaccination

Notes:

[7] - 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 is descriptive in nature, no statistical analysis is provided.

[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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	155	79	196	96
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	67.1 (59.1 to 74.4)	69.6 (58.2 to 79.5)	56.1 (48.9 to 63.2)	71.9 (61.8 to 80.6)
Serogroup C	100.0 (97.6 to 100)	98.7 (93.1 to 100.0)	90.8 (85.9 to 94.5)	91.7 (84.2 to 96.3)
Serogroup Y	92.3 (86.9 to 95.9)	87.3 (78.0 to 93.8)	92.9 (88.3 to 96.0)	92.7 (85.6 to 97.0)
Serogroup W	82.6 (75.7 to 88.2)	82.3 (72.1 to 90.0)	82.1 (76.1 to 87.2)	90.6 (82.9 to 95.6)

End point values	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+ Varicella Vaccine	Groups 2 and 11: MenACYW Conjugate Vaccine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	177	87		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A	78.5 (71.7 to 84.3)	63.2 (52.2 to 73.3)		
Serogroup C	97.7 (94.3 to 99.4)	98.9 (93.8 to 100.0)		
Serogroup Y	93.2 (88.5 to 96.4)	88.5 (79.9 to 94.3)		
Serogroup W	86.4 (80.5 to 91.1)	83.9 (74.5 to 90.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of MMR-Varicella Antibodies Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12

End point title	Geometric Mean Titers of MMR-Varicella Antibodies Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12

End point description:

Antibodies titers of Measles and Rubella were measured by enzyme immunoassay (EIA). Antibodies titers for mumps and varicella were measured by enzyme-linked immunosorbent assay (ELISA). Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 3 and 12. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 2, 4, 5, 6, 7, 8, 9, and 11.

End point type	Secondary

End point timeframe:

Day 0 and Day 30 post-vaccination

End point values	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+ Varicella Vaccine	Groups 3 and 12: MMR + Varicella Vaccine		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	177	92		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
Measles: Day 0 (n=176,92)	40.0 (37.2 to 43.1)	45.0 (40.1 to 50.4)		
Measles: Day 30 (n=177,92)	2156 (1893 to 2455)	2840 (2389 to 3378)		
Mumps: Day 0 (n=176,92)	5.51 (5.20 to 5.84)	5.43 (5.05 to 5.83)		
Mumps: Day 30 (n=177,92)	85.9 (74.7 to 98.7)	97.6 (83.1 to 115)		
Rubella: Day 0 (n=176,92)	5.94 (5.32 to 6.63)	7.12 (6.07 to 8.34)		
Rubella: Day 30 (n=177,92)	87.6 (79.4 to 96.7)	104 (91.2 to 118)		
Varicella: Day 0 (n=176,92)	0.556 (0.484 to 0.638)	0.665 (0.508 to 0.869)		
Varicella: Day 30 (n=177,92)	13.4 (11.6 to 15.4)	17.4 (15.2 to 19.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immune Response Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12

End point title	Percentage of Subjects With Immune Response Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12

End point description:

Immune response for MMR-Varicella vaccine was defined as: anti-measles Antibody (Ab) concentrations >=255 milli-international unit per milliliter (mIU/mL), anti-mumps Ab concentrations: >=10 Ab units/mL, anti-rubella Ab concentrations >=10 international unit per milliliter (IU/mL),anti-varicella Ab concentrations >=5 glycoprotein enzyme-linked immunosorbent assay (gpELISA) Ab units/mL. Data for this endpoint was planned to be analysed and reported for the combined population of Groups 1 and 10, Groups 3 and 12. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 2, 4, 5, 6, 7, 8, 9, and 11.

End point type	Secondary

End point timeframe:

Day 0 and Day 30 post-vaccination

End point values	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+ Varicella Vaccine	Groups 3 and 12: MMR + Varicella Vaccine		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	177	92		
Units: percentage of subjects				
number (confidence interval 95%)				
Measles: Day 0 (n=176,92)	0.6 (0.0 to 3.1)	0.0 (0.0 to 3.9)		
Measles: Day 30 (n=177,92)	96.6 (92.8 to 98.7)	97.8 (92.4 to 99.7)		
Mumps: Day 0 (n=176,92)	7.4 (4.0 to 12.3)	6.5 (2.4 to 13.7)		
Mumps: Day 30 (n=177,92)	97.7 (94.3 to 99.4)	100.0 (96.1 to 100.0)		
Rubella: Day 0 (n=176,92)	27.3 (20.8 to 34.5)	31.5 (22.2 to 42.0)		
Rubella: Day 30 (n=177,92)	100.0 (97.9 to 100)	100.0 (96.1 to 100)		
Varicella: Day 0 (n=176,92)	4.0 (1.6 to 8.0)	7.6 (3.1 to 15.1)		
Varicella: Day 30 (n=177,92)	93.2 (88.5 to 96.4)	98.9 (94.1 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Pertussis Toxoid (PT) and Filamentous Hemagglutinin (FHA) Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administrated Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6

End point title	Geometric Mean Titers of Pertussis Toxoid (PT) and Filamentous Hemagglutinin (FHA) Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administrated Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6[9]

End point description:

Antibodies titers of PT and FHA were measured by electrochemiluminescent (ECL) assay. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11, and 12.

End point type	Secondary

End point timeframe:

Day 0 and Day 30 post-vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	68		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				

PT: Day 0	17.9 (15.1 to 21.3)	20.4 (15.3 to 27.0)		
PT: Day 30	144 (130 to 159)	169 (144 to 198)		
FHA: Day 0	45.5 (37.0 to 55.9)	57.4 (41.4 to 79.5)		
FHA: Day 30	299 (265 to 337)	391 (319 to 480)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of DTaP-IPV-HB-Hib Antibodies Following Injection With DTaP-IPV-HB-Hib Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 4 and 6

End point title	Geometric Mean Titers of DTaP-IPV-HB-Hib Antibodies Following Injection With DTaP-IPV-HB-Hib Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 4 and 6[10]

End point description:

Antibodies titers of Diphtheria, Tetanus and Pertussis were meausured by ECL assay. Antibodies titers of poliovirus types 1, 2, and 3 were measured by neutralization assay. Antibodies titers of Hepatitis B were measured by an immunodiagnostic system using chemiluminescence detection. Antibodies titers of Polyribosyl-ribitol phosphate (PRP) were measured by Farr-type radioimmunoassay (RIA). Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11, and 12.

End point type	Secondary

End point timeframe:

Day 0 (for tetanus only) and Day 30 post-vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	68		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
Diphtheria: Day 30 (n =155,68)	5.52 (4.94 to 6.17)	6.34 (5.51 to 7.30)		
Tetanus: Day 0 (n =155, 67)	0.238 (0.196 to 0.289)	0.234 (0.177 to 0.309)		
Tetanus: Day 30 (n =155,68)	7.06 (6.01 to 8.29)	7.11 (5.79 to 8.74)		
Polio 1: Day 30 (n=155,68)	4560 (3870 to 5373)	4034 (3052 to 5332)		
Polio 2: Day 30 (n=155,68)	7244 (6208 to 8453)	5618 (4578 to 6895)		

Polio 3: Day 30 (n=155,68)	5977 (4958 to 7205)	5100 (3840 to 6772)		
Hepatitis B: Day 30 (n=155,68)	5171 (4104 to 6515)	7308 (5135 to 10401)		
PRP: Day30 (n=155,68)	46.6 (39.6 to 54.9)	56.2 (41.5 to 76.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immune Response Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6

End point title	Percentage of Subjects With Immune Response Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6[11]

End point description:

Immune response for DTaP-IPV-HB-Hib vaccine was defined as: anti-tetanus Ab concentrations: >=0.01 and 0.1 IU/mL at Day 0 and >=0.1 and 1.0 IU/mL at Day 30, anti-diphtheria Ab concentrations: >=0.1 and 1.0 IU/mL, anti-PRP Ab concentrations and >= 0.15 and 1.0 microgram per milliliter (mcg/mL), anti-poliovirus types 1, 2, and 3 Ab titers >=1:8, anti-hepatitis B surface antigen Ab concentrations >=10 mIU/mL, >=100 mIU/mL. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11 and 12.

End point type	Secondary

End point timeframe:

Day 0 (tetanus only) and Day 30 post-vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	68		
Units: Percentage of subjects				
number (confidence interval 95%)				
Diphtheria: Day 30 (>=0.1 IU/mL)(n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
Diphtheria: Day 30 (>=1 IU/mL) (n=155,68)	98.7 (95.4 to 99.8)	100.0 (94.7 to 100)		
Tetanus: Day 0 (>=0.01 IU/mL) (n=155,67)	100.0 (97.6 to 100)	100.0 (94.6 to 100)		
Tetanus: Day 0 (>=0.1 IU/mL) (n=155,67)	81.3 (74.2 to 87.1)	77.6 (65.8 to 86.9)		
Tetanus: Day 30 (>=0.1 IU/mL) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
Tetanus: Day 30 (>=1 IU/mL) (n=155,68)	98.1 (94.4 to 99.6)	98.5 (92.1 to 100.0)		

Polio 1: Day 30 (>=8 [1/dilution]) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
Polio 2: Day 30 (>=8 [1/dilution]) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
Polio 3: Day 30 (>=8 [1/dilution]) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
Hepatitis B: Day 30 (>=10 mIU/mL) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
Hepatitis B: Day 30 (>=100 mIU/mL) (n=155,68)	98.7 (95.4 to 99.8)	100.0 (94.7 to 100)		
PRP: Day 30 (>=0.15 mcg/mL) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		
PRP: Day 30 (>=1.0 mcg/mL) (n=155,68)	100.0 (97.6 to 100)	100.0 (94.7 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Response of PT and FHA Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6

End point title	Percentage of Subjects With Vaccine Response of PT and FHA Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6[12]

End point description:

Pertussis and FHA vaccine response was defined as: if the pre-vaccination concentration is < 4 * lower limit of quantification (LLOQ is equal to 2), then the post-vaccination concentration is >=4 * pre-vaccination concentration and if the pre-vaccination concentration is >= 4 * LLOQ, then the post-vaccination concentration is >= 2 * pre-vaccination concentration. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11, and 12.

End point type	Secondary

End point timeframe:

Day 0 and Day 30 post-vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	68		
Units: percentage of subjects				
number (confidence interval 95%)				
PT: Day 30/Day 0	91.0 (85.3 to 95.0)	92.6 (83.7 to 97.6)		
FHA: Day 30/Day 0	89.0 (83.0 to 93.5)	88.2 (78.1 to 94.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of PCV13 Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F Antibodies Following Injection With PCV13 Vaccine Administrated Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 7 and 9

End point title	Geometric Mean Titers of PCV13 Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F Antibodies Following Injection With PCV13 Vaccine Administrated Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 7 and 9[13]

End point description:

Antibodies of pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F were measured by ECL assay. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 4, 5, 6, 8, 10, 11, and 12.

End point type	Secondary

End point timeframe:

Day 0 and Day 30 post-vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 9): PCV13 Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	92		
Units: titers (1/dilution)				
geometric mean (confidence interval 95%)				
Serotype 1: Day 0 (n=193,92)	0.867 (0.741 to 1.01)	0.918 (0.713 to 1.18)		
Serotype 1: Day 30 (n=191,92)	2.33 (1.98 to 2.75)	2.14 (1.63 to 2.81)		
Serotype 3: Day 0 (n=193,92)	0.409 (0.341 to 0.491)	0.414 (0.322 to 0.533)		
Serotype 3: Day 30 (n=191,92)	0.802 (0.664 to 0.967)	0.773 (0.608 to 0.983)		
Serotype 4: Day 0 (n=193,92)	0.604 (0.511 to 0.715)	0.653 (0.507 to 0.840)		
Serotype 4: Day 30 (n=191,92)	1.97 (1.68 to 2.31)	1.49 (1.15 to 1.93)		
Serotype 5: Day 0 (n=193,92)	0.828 (0.719 to 0.953)	0.782 (0.610 to 1.00)		

Serotype 5: Day 30 (n=191,92)	1.99 (1.70 to 2.31)	1.73 (1.33 to 2.24)		
Serotype 6A: Day 0 (n=193,92)	1.61 (1.33 to 1.95)	1.48 (1.09 to 2.00)		
Serotype 6A: Day 30 (n=191,92)	5.96 (4.99 to 7.13)	6.13 (4.47 to 8.41)		
Serotype 6B: Day 0 (n=193,92)	0.895 (0.715 to 1.12)	0.691 (0.514 to 0.929)		
Serotype 6B: Day 30 (n=191,92)	3.66 (2.99 to 4.50)	2.57 (1.83 to 3.61)		
Serotype 7F: Day 0 (n=193,92)	1.32 (1.12 to 1.55)	1.39 (1.08 to 1.77)		
Serotype 7F: Day 30 (n=191,92)	3.05 (2.59 to 3.58)	2.67 (2.05 to 3.47)		
Serotype 9V: Day 0 (n=193,92)	0.841 (0.710 to 0.997)	0.863 (0.660 to 1.13)		
Serotype 9V: Day 30 (n=191,92)	2.34 (1.95 to 2.81)	2.52 (1.92 to 3.30)		
Serotype 14: Day 0 (n=192,92)	3.25 (2.74 to 3.86)	3.00 (2.30 to 3.91)		
Serotype 14: Day 30 (n=191,92)	7.62 (6.56 to 8.83)	6.30 (5.00 to 7.93)		
Serotype 18C: Day 0 (n=193,92)	0.737 (0.620 to 0.876)	0.995 (0.766 to 1.29)		
Serotype 18C: Day 30 (n=191,92)	2.19 (1.87 to 2.58)	2.21 (1.73 to 2.83)		
Serotype 19A: Day 0 (n=193,92)	1.65 (1.36 to 2.01)	1.96 (1.46 to 2.64)		
Serotype 19A: Day 30 (n=191,92)	5.75 (4.85 to 6.80)	5.91 (4.54 to 7.69)		
Serotype 19F: Day 0 (n=193,92)	1.78 (1.43 to 2.21)	1.74 (1.28 to 2.35)		
Serotype 19F: Day 30 (n=191,92)	5.58 (4.57 to 6.81)	5.53 (3.98 to 7.69)		
Serotype 23F: Day 0 (n=192,92)	0.631 (0.519 to 0.768)	0.733 (0.537 to 1.00)		
Serotype 23F: Day 30 (n=191,92)	2.42 (2.04 to 2.86)	2.58 (1.98 to 3.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immune Response Following Injection With PCV13 Vaccine Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 7 and 9

End point title	Percentage of Subjects With Immune Response Following Injection With PCV13 Vaccine Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 7 and 9[14]

End point description:

Immune response for PCV13 for serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F was defined as antibodies concentrations >=0.35 mcg/mL or >=1.0 mcg/mL. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 4, 5, 6, 8, 10, 11, and 12.

End point type	Secondary

End point timeframe:

Day 0 and Day 30 post-vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 9): PCV13 Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	92		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 1: Day 0 (>=0.35 mcg/mL)(n=193,92)	80.8 (74.6 to 86.1)	79.3 (69.6 to 87.1)		
Serotype 1: Day 0 (>=1.0 mcg/mL) (n=193,92)	43.0 (35.9 to 50.3)	45.7 (35.2 to 56.4)		
Serotype 1: Day 30 (>=0.35 mcg/mL) (n=191,92)	97.4 (94.0 to 99.1)	94.6 (87.8 to 98.2)		
Serotype 1: Day 30 (>=1.0 mcg/mL) (n=191,92)	76.4 (69.8 to 82.3)	70.7 (60.2 to 79.7)		
Serotype 3: Day 0 (>=0.35 mcg/mL) (n=193,92)	49.2 (42.0 to 56.5)	53.3 (42.6 to 63.7)		
Serotype 3: Day 0 (>=1.0 mcg/mL) (n=193,92)	22.3 (16.6 to 28.8)	18.5 (11.1 to 27.9)		
Serotype 3: Day 30 (>=0.35 mcg/mL) (n=191,92)	72.3 (65.3 to 78.5)	76.1 (66.1 to 84.4)		
Serotype 3: Day 30 (>=1.0 mcg/mL) (n=191,92)	48.2 (40.9 to 55.5)	38.0 (28.1 to 48.8)		
Serotype 4: Day 0 (>=0.35 mcg/mL) (n=193,92)	66.8 (59.7 to 73.4)	68.5 (58.0 to 77.8)		
Serotype 4: Day 0 (>=1.0 mcg/mL) (n=193,92)	33.7 (27.1 to 40.8)	38.0 (28.1 to 48.8)		
Serotype 4: Day 30 (>=0.35 mcg/mL) (n=191,92)	92.7 (88.0 to 95.9)	90.2 (82.2 to 95.4)		
Serotype 4: Day 30 (>=1.0 mcg/mL) (n=191,92)	80.1 (73.7 to 85.5)	62.0 (51.2 to 71.9)		
Serotype 5: Day 0 (>=0.35 mcg/mL) (n=193,92)	81.3 (75.1 to 86.6)	76.1 (66.1 to 84.4)		
Serotype 5: Day 0 (>=1.0 mcg/mL) (n=193,92)	41.5 (34.4 to 48.7)	50.0 (39.4 to 60.6)		
Serotype 5: Day 30 (>=0.35 mcg/mL) (n=191,92)	94.8 (90.6 to 97.5)	90.2 (82.2 to 95.4)		
Serotype 5: Day 30 (>=1.0 mcg/mL) (n=191,92)	71.2 (64.2 to 77.5)	69.6 (59.1 to 78.7)		
Serotype 6A: Day 0 (>=0.35 mcg/mL) (n=193,92)	90.2 (85.1 to 94.0)	82.6 (73.3 to 89.7)		
Serotype 6A: Day 0 (>=1.0 mcg/mL) (n=193,92)	63.7 (56.5 to 70.5)	65.2 (54.6 to 74.9)		
Serotype 6A: Day 30 (>=0.35 mcg/mL) (n=191,92)	97.4 (94.0 to 99.1)	96.7 (90.8 to 99.3)		
Serotype 6A: Day 30 (>=1.0 mcg/mL) (n=191,92)	96.3 (92.6 to 98.5)	90.2 (82.2 to 95.4)		
Serotype 6B: Day 0 (>=0.35 mcg/mL) (n=193,92)	72.0 (65.1 to 78.2)	68.5 (58.0 to 77.8)		
Serotype 6B: Day 0 (>=1.0 mcg/mL) (n=193,92)	44.6 (37.4 to 51.9)	41.3 (31.1 to 52.1)		

Serotype 6B: Day 30 (>=0.35 mcg/mL) (n=191,92)	94.8 (90.6 to 97.5)	92.4 (84.9 to 96.9)		
Serotype 6B: Day 30 (>=1.0 mcg/mL) (n=191,92)	86.4 (80.7 to 90.9)	75.0 (64.9 to 83.4)		
Serotype 7F: Day 0 (>=0.35 mcg/mL) (n=193,92)	87.0 (81.5 to 91.4)	88.0 (79.6 to 93.9)		
Serotype 7F: Day 0 (>=1.0 mcg/mL) (n=193,92)	62.7 (55.5 to 69.5)	65.2 (54.6 to 74.9)		
Serotype 7F: Day 30 (>=0.35 mcg/mL) (n=191,92)	98.4 (95.5 to 99.7)	94.6 (87.8 to 98.2)		
Serotype 7F: Day 30 (>=1.0 mcg/mL) (n=191,92)	80.1 (73.7 to 85.5)	83.7 (74.5 to 90.6)		
Serotype 9V: Day 0 (>=0.35 mcg/mL) (n=193,92)	77.2 (70.6 to 82.9)	79.3 (69.6 to 87.1)		
Serotype 9V: Day 0 (>=1.0 mcg/mL) (n=193,92)	42.0 (34.9 to 49.3)	43.5 (33.2 to 54.2)		
Serotype 9V: Day 30 (>=0.35 mcg/mL) (n=191,92)	95.3 (91.2 to 97.8)	92.4 (84.9 to 96.9)		
Serotype 9V: Day 30 (>=1.0 mcg/mL) (n=191,92)	74.3 (67.5 to 80.4)	75.0 (64.9 to 83.4)		
Serotype 14: Day 0 (>=0.35 mcg/mL) (n=192,92)	95.8 (92.0 to 98.2)	92.4 (84.9 to 96.9)		
Serotype 14: Day 0 (>=1.0 mcg/mL) (n=192,92)	83.3 (77.3 to 88.3)	87.0 (78.0 to 93.1)		
Serotype 14: Day 30 (>=0.35 mcg/mL) (n=191,92)	99.0 (96.3 to 99.9)	98.9 (94.1 to 100.0)		
Serotype 14: Day 30 (>=1.0 mcg/mL) (n=191,92)	97.4 (94.0 to 99.1)	94.6 (87.8 to 98.2)		
Serotype 18C: Day 0 (>=0.35 mcg/mL) (n=193,92)	71.5 (64.6 to 77.8)	84.8 (75.8 to 91.4)		
Serotype 18C: Day 0 (>=1.0 mcg/mL) (n=193,92)	40.9 (33.9 to 48.2)	48.9 (38.3 to 59.6)		
Serotype 18C: Day 30 (>=0.35 mcg/mL) (n=191,92)	95.3 (91.2 to 97.8)	92.4 (84.9 to 96.9)		
Serotype 18C: Day 30 (>=1.0 mcg/mL) (n=191,92)	79.1 (72.6 to 84.6)	79.3 (69.6 to 87.1)		
Serotype 19A: Day 0 (>=0.35 mcg/mL) (n=193,92)	87.0 (81.5 to 91.4)	87.0 (78.3 to 93.1)		
Serotype 19A: Day 0 (>=1.0 mcg/mL) (n=193,92)	62.7 (55.5 to 69.5)	69.6 (59.1 to 78.7)		
Serotype 19A: Day 30 (>=0.35 mcg/mL) (n=191,92)	96.3 (92.6 to 98.5)	98.9 (94.1 to 100.0)		
Serotype 19A: Day 30 (>=1.0 mcg/mL) (n=191,92)	92.7 (88.0 to 95.9)	90.2 (82.2 to 95.4)		
Serotype 19F: Day 0 (>=0.35 mcg/mL) (n=193,92)	87.0 (81.5 to 91.4)	89.1 (80.9 to 94.7)		
Serotype 19F: Day 0 (>=1.0 mcg/mL) (n=193,92)	64.2 (57.0 to 71.0)	65.2 (54.6 to 74.9)		
Serotype 19F: Day 30 (>=0.35 mcg/mL) (n=191,92)	96.9 (93.3 to 98.8)	97.8 (92.4 to 99.7)		
Serotype 19F: Day 30 (>=1.0 mcg/mL) (n=191,92)	88.0 (82.5 to 92.2)	85.9 (77.0 to 92.3)		
Serotype 23F: Day 0 (>=0.35 mcg/mL) (n=192,92)	68.2 (61.1 to 74.7)	64.1 (53.5 to 73.9)		
Serotype 23F: Day 0 (>=1.0 mcg/mL) (n=192,92)	34.9 (28.2 to 42.1)	44.6 (34.2 to 55.3)		
Serotype 23F: Day 30 (>=0.35 mcg/mL) (n=191,92)	96.3 (92.6 to 98.5)	93.5 (86.3 to 97.6)		
Serotype 23F: Day 30 (>=1.0 mcg/mL) (n=191,92)	72.3 (65.3 to 78.5)	78.3 (68.4 to 86.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 1, 2, 3, 10, 11 and 12

End point title	Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 1, 2, 3, 10, 11 and 12[15]

End point description:

Solicited injection site reactions: tenderness, erythema and swelling. Tenderness: Grade 3: cries when injected limb moved, or the movement of the injected limb reduced, Erythema and swelling: Grade 3: >= 50 millimeter (mm). Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on safety analysis set which included all subjects who received at least 1 dose of study vaccine and had any safety data available. Here, '99999' was used as space fillers and indicate that vaccine was not administered to the specified group.

End point type	Secondary

End point timeframe:

Within 7 days post vaccination

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 for Groups 4, 5, 6, 7, 8, and 9 are reported in separate endpoints.

End point values	South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine	South Korea (Group 2): MenACYW Conjugate Vaccine	South Korea (Group 3): MMR + Varicella Vaccine	Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	103	52	53	86
Units: subjects				
number (not applicable)				
MenACYW: Tenderness: Any Grade	28	15	99999	25
MenACYW: Tenderness: Grade 3	1	0	99999	0
MenACYW: Erythema: Any Grade	27	20	99999	21
MenACYW: Erythema: Grade 3	0	2	99999	0
MenACYW: Swelling: Any Grade	18	14	99999	13
MenACYW: Swelling: Grade 3	0	0	99999	0
MMR: Tenderness: Any Grade	21	99999	10	17
MMR: Tenderness: Grade 3	1	99999	0	0
MMR: Erythema: Any Grade	13	99999	6	17
MMR: Erythema: Grade 3	0	99999	0	0
MMR: Swelling: Any Grade	7	99999	1	11
MMR: Swelling: Grade 3	0	99999	0	0
Varicella: Tenderness: Any Grade	23	99999	11	15
Varicella: Tenderness: Grade 3	0	99999	0	0

Varicella: Erythema: Any Grade	19	99999	4	13
Varicella: Erythema: Grade 3	1	99999	0	0
Varicella: Swelling: Any Grade	10	99999	2	11
Varicella: Swelling: Grade 3	0	99999	0	0

End point values	Thailand (Group 11): MenACYW Conjugate Vaccine	Thailand (Group 12): MMR + Varicella Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	42		
Units: subjects				
number (not applicable)				
MenACYW: Tenderness: Any Grade	15	99999		
MenACYW: Tenderness: Grade 3	1	99999		
MenACYW: Erythema: Any Grade	6	99999		
MenACYW: Erythema: Grade 3	0	99999		
MenACYW: Swelling: Any Grade	5	99999		
MenACYW: Swelling: Grade 3	0	99999		
MMR: Tenderness: Any Grade	99999	17		
MMR: Tenderness: Grade 3	99999	0		
MMR: Erythema: Any Grade	99999	6		
MMR: Erythema: Grade 3	99999	0		
MMR: Swelling: Any Grade	99999	3		
MMR: Swelling: Grade 3	99999	0		
Varicella: Tenderness: Any Grade	99999	13		
Varicella: Tenderness: Grade 3	99999	1		
Varicella: Erythema: Any Grade	99999	6		
Varicella: Erythema: Grade 3	99999	0		
Varicella: Swelling: Any Grade	99999	4		
Varicella: Swelling: Grade 3	99999	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 4, 5 and 6

End point title	Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 4, 5 and 6[16]

End point description:

Solicited injection site reactions: tenderness, erythema and swelling. Tenderness: Grade 3: cries when injected limb moved, or the movement of the injected limb reduced, Erythema and swelling: Grade 3: >= 50 mm. Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on safety analysis set. Here, 'n' = subjects with available data for each specified category. Here, '99999' was used as space fillers and indicate that vaccine was not administered to the specified group.

End point type	Secondary

End point timeframe:

Within 7 days post vaccination

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: This endpoint was evaluated for reported arms only.

End point values	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	200	100	100	
Units: subjects				
number (not applicable)				
MenACYW: Tenderness: Any Grade(n=191,98,100)	68	27	99999	
MenACYW: Tenderness: Grade 3 (n=191,98,100)	6	1	99999	
MenACYW: Erythema: Any Grade (n=191,98,100)	40	15	99999	
MenACYW: Erythema: Grade 3 (n=191,98,100)	3	3	99999	
MenACYW: Swelling: Any Grade (n=191,98,100)	23	8	99999	
MenACYW: Swelling: Grade 3 (n=191,98,100)	2	2	99999	
DTaP-IPV-HB-Hib:Tenderness:Any Grade(n=191,100,95)	80	99999	54	
DTaP-IPV-HB-Hib: Tenderness:Grade 3 (n=191,100,95)	6	99999	10	
DTaP-IPV-HB-Hib: Erythema:Any Grade (n=191,100,95)	56	99999	37	
DTaP-IPV-HB-Hib: Erythema: Grade 3 (n=191,100,95)	8	99999	5	
DTaP-IPV-HB-Hib: Swelling:Any Grade (n=191,100,95)	45	99999	30	
DTaP-IPV-HB-Hib: Swelling: Grade 3 (n=191,100,95)	8	99999	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 7, 8 and 9

End point title	Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 7, 8 and 9[17]

End point description:

Solicited injection site reactions: tenderness, erythema and swelling. Tenderness: Grade 3: cries when injected limb moved, or the movement of the injected limb reduced, Erythema and swelling: Grade 3: >= 50 mm. Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on Safety analysis set. Here, '99999' was used as space fillers and indicate that vaccine was not administered to the specified group.

End point type	Secondary

End point timeframe:

Within 07 days post vaccination

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 for Groups 1, 2, 3, 10, 11, 12, 4, 5, and 6 are reported in separate endpoints.

End point values	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine	Russian Federation (Group 9): PCV13 Vaccine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	200	100	99	
Units: subjects				
number (not applicable)				
MenACYW: Tenderness: Any Grade	28	8	99999	
MenACYW: Tenderness: Grade 3	4	0	99999	
MenACYW: Erythema: Any Grade	43	17	99999	
MenACYW: Erythema: Grade 3	0	0	99999	
MenACYW: Swelling: Any Grade	8	7	99999	
MenACYW: Swelling: Grade 3	0	0	99999	
PCV13: Tenderness: Any Grade	34	99999	9	
PCV13: Tenderness: Grade 3	5	99999	1	
PCV13: Erythema: Any Grade	48	99999	8	
PCV13: Erythema: Grade 3	0	99999	0	
PCV13: Swelling: Any Grade	19	99999	2	
PCV13: Swelling: Grade 3	0	99999	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Systemic Reactions (Fever, Vomiting, Abnormal Crying, Drowsiness, Appetite Loss, Irritability)

End point title	Number of Subjects Reporting at Least One Solicited Systemic Reactions (Fever, Vomiting, Abnormal Crying, Drowsiness, Appetite Loss, Irritability)

End point description:

Solicited systemic reaction: Fever: Grade 3: > 39.5°C, Vomiting: Grade 3: >= 6 episodes per 24 hours or requiring parenteral hydration, Crying abnormal: Grade 3: >3 hours, Drowsiness: Grade 3: sleeping most of the time or difficult to wake up, Appetite lost: Grade 3: refuses >= 3 feeds/meals or refuses most feeds/meals, Irritability: Grade 3: inconsolable. Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on Safety analysis set. Here, 'number of subjects analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Within 07 days post vaccination

End point values	South Korea(Group1) : MenACYW Conjugate +MMR+ Varicella Vaccine	South Korea (Group 2): MenACYW Conjugate Vaccine	South Korea (Group 3): MMR + Varicella Vaccine	Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	103	52	53	86
Units: subjects				
number (not applicable)				
Fever: Any Grade	17	9	5	6
Fever: Grade 3	1	2	1	0
Vomiting: Any Grade	6	3	2	5
Vomiting: Grade 3	0	0	0	0
Abnormal crying: Any Grade	21	9	6	14
Abnormal crying: Grade 3	0	0	0	0
Drowsiness: Any Grade	17	8	9	8
Drowsiness: Grade 3	0	0	0	0
Appetite Lost: Any Grade	29	10	8	11
Appetite Lost: Grade 3	1	0	0	0
Irritability: Any Grade	31	12	11	14
Irritability: Grade 3	0	0	0	0

End point values	Thailand (Group 11): MenACYW Conjugate Vaccine	Thailand (Group 12): MMR + Varicella Vaccine	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	42	191	98
Units: subjects				
number (not applicable)				
Fever: Any Grade	1	3	32	7
Fever: Grade 3	1	0	4	1
Vomiting: Any Grade	4	5	15	6
Vomiting: Grade 3	0	1	0	1
Abnormal crying: Any Grade	14	12	46	25
Abnormal crying: Grade 3	0	0	1	1
Drowsiness: Any Grade	7	7	31	15
Drowsiness: Grade 3	0	1	1	0
Appetite Lost: Any Grade	12	5	51	25
Appetite Lost: Grade 3	0	2	8	2
Irritability: Any Grade	11	14	64	34
Irritability: Grade 3	1	0	4	1

End point values	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine	Russian Federation (Group 9): PCV13 Vaccine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	200	100	99
Units: subjects				
number (not applicable)				
Fever: Any Grade	16	12	3	2
Fever: Grade 3	0	0	0	0
Vomiting: Any Grade	9	0	0	0
Vomiting: Grade 3	0	0	0	0
Abnormal crying: Any Grade	26	8	4	2
Abnormal crying: Grade 3	1	2	0	0
Drowsiness: Any Grade	17	25	6	4
Drowsiness: Grade 3	2	1	0	0
Appetite Lost: Any Grade	20	19	12	7
Appetite Lost: Grade 3	3	1	0	0
Irritability: Any Grade	33	26	16	9
Irritability: Grade 3	3	4	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event (AE) data were collected from Day 0 up to Day 30 post-vaccination and solicited reaction (SR) data within 7 days after vaccination.Serious adverse event (SAE) data were collected throughout the study period (up to Day 30 post-vaccination)

Adverse event reporting additional description:

Safety Analysis Set. A SR was an AE that was prelisted (i.e., solicited) in the electronic case report form (eCRF) and considered to be related to vaccination (adverse drug reaction). An unsolicited AE was an observed AE that did not fulfill the conditions prelisted (i.e., solicited) in the eCRF in terms of symptom and/or onset post-vaccination.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	South Korea(Group1):MenACYW Conjugate +MMR +Varicella Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine, MMR vaccine, and varicella vaccine on Day 0.

Reporting group title	South Korea (Group 2): MenACYW Conjugate Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

Reporting group title	South Korea (Group 3): MMR + Varicella Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and Varicella vaccine on Day 0.

Reporting group title	Thailand (Group 10):MenACYW Conjugate + MMR+ Varicella Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine, MMR, vaccine and varicella vaccine on Day 0.

Reporting group title	Thailand (Group 11): MenACYW Conjugate Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

Reporting group title	Thailand (Group 12): MMR + Varicella Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.

Reporting group title	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+Varicella Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW Conjugate vaccine, MMR vaccine, and varicella vaccine on Day 0.

Reporting group title	Groups 2 and 11: MenACYW Conjugate Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW Conjugate vaccine on Day 0.

Reporting group title	Groups 3 and 12: MMR + Varicella Vaccine

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand

received single dose of MMR vaccine and varicella vaccine on Day 0.

Reporting group title	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and DTaP-IPV-HB-Hib vaccine on Day 0.	
Reporting group title	Mexico (Group 5): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0.	
Reporting group title	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate vaccine and PCV13 vaccine on Day 0.	
Reporting group title	Russian Federation (Group 8): MenACYW Conjugate Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.	
Reporting group title	Russian Federation (Group 9): PCV13 Vaccine
Reporting group description:	
Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13 vaccine on Day 0.	

Serious adverse events	South Korea(Group1):MenACYW Conjugate +MMR +Varicella	South Korea (Group 2): MenACYW Conjugate Vaccine	South Korea (Group 3): MMR + Varicella Vaccine
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 103 (5.83%)	4 / 52 (7.69%)	2 / 53 (3.77%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 52 (0.00%)	0 / 53 (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

Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 103 (0.00%)	2 / 52 (3.85%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 52 (1.92%)	0 / 53 (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
Bronchitis Viral			
subjects affected / exposed	2 / 103 (1.94%)	0 / 52 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup Infectious			
subjects affected / exposed	0 / 103 (0.00%)	0 / 52 (0.00%)	0 / 53 (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
Gastroenteritis			
subjects affected / exposed	1 / 103 (0.97%)	1 / 52 (1.92%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	1 / 103 (0.97%)	1 / 52 (1.92%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Media Viral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
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 Viral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 52 (0.00%)	1 / 53 (1.89%)
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 Syncytial Virus			

Bronchiolitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 52 (0.00%)	0 / 53 (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
Tonsillitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 52 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Thailand (Group 10):MenACYW Conjugate + MMR+ Varicella Vaccine	Thailand (Group 11): MenACYW Conjugate Vaccine	Thailand (Group 12): MMR + Varicella Vaccine
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 86 (0.00%)	1 / 42 (2.38%)	0 / 42 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Bronchitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Bronchitis Viral			

subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Croup Infectious			
subjects affected / exposed	0 / 86 (0.00%)	1 / 42 (2.38%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Otitis Media Viral			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Viral			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Tonsillitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (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	Groups 1 and10:MenACYW	Groups 2 and 11: MenACYW Conjugate	Groups 3 and 12: MMR + Varicella

	Vaccine+MMR+Varicella Vaccine	Vaccine	Vaccine
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 189 (3.17%)	5 / 94 (5.32%)	2 / 95 (2.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 189 (0.00%)	0 / 94 (0.00%)	0 / 95 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 189 (0.00%)	0 / 94 (0.00%)	0 / 95 (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
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 189 (0.00%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 189 (0.00%)	1 / 94 (1.06%)	0 / 95 (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
Bronchitis Viral			
subjects affected / exposed	2 / 189 (1.06%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup Infectious			
subjects affected / exposed	0 / 189 (0.00%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 189 (0.53%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	1 / 189 (0.53%)	1 / 94 (1.06%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Media Viral			
subjects affected / exposed	0 / 189 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
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 Viral			
subjects affected / exposed	0 / 189 (0.00%)	0 / 94 (0.00%)	1 / 95 (1.05%)
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 Syncytial Virus Bronchiolitis			
subjects affected / exposed	1 / 189 (0.53%)	0 / 94 (0.00%)	0 / 95 (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
Tonsillitis			
subjects affected / exposed	1 / 189 (0.53%)	0 / 94 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			

subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
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			
Asthma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Bronchitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Bronchitis Viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Croup Infectious			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Gastroenteritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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

Otitis Media Viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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
Tonsillitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (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	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine	Russian Federation (Group 9): PCV13 Vaccine
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Infections and infestations			

Bronchiolitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Bronchitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Bronchitis Viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Croup Infectious			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Gastroenteritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Otitis Media Viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Respiratory Syncytial Virus Bronchiolitis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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
Tonsillitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (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

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

Non-serious adverse events	South Korea(Group1):Men ACYW Conjugate +MMR +Varicella	South Korea (Group 2): MenACYW Conjugate Vaccine	South Korea (Group 3): MMR + Varicella Vaccine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	85 / 103 (82.52%)	43 / 52 (82.69%)	37 / 53 (69.81%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	17 / 103 (16.50%)	8 / 52 (15.38%)	9 / 53 (16.98%)
occurrences (all)	17	8	9
General disorders and administration site conditions			
Crying			
subjects affected / exposed	21 / 103 (20.39%)	9 / 52 (17.31%)	6 / 53 (11.32%)
occurrences (all)	21	9	6
Injection Site Erythema			
subjects affected / exposed	35 / 103 (33.98%)	20 / 52 (38.46%)	8 / 53 (15.09%)
occurrences (all)	60	20	10
Injection Site Pain			
subjects affected / exposed	31 / 103 (30.10%)	15 / 52 (28.85%)	12 / 53 (22.64%)
occurrences (all)	72	15	21
Injection Site Swelling			
subjects affected / exposed	25 / 103 (24.27%)	14 / 52 (26.92%)	3 / 53 (5.66%)
occurrences (all)	35	14	3
Pyrexia			
subjects affected / exposed	21 / 103 (20.39%)	11 / 52 (21.15%)	10 / 53 (18.87%)
occurrences (all)	21	12	12
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	3 / 103 (2.91%)	2 / 52 (3.85%)	0 / 53 (0.00%)
occurrences (all)	3	2	0
Vomiting			
subjects affected / exposed	7 / 103 (6.80%)	3 / 52 (5.77%)	2 / 53 (3.77%)
occurrences (all)	7	3	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 103 (2.91%)	0 / 52 (0.00%)	5 / 53 (9.43%)
occurrences (all)	3	0	5
Rhinorrhoea			
subjects affected / exposed	1 / 103 (0.97%)	3 / 52 (5.77%)	4 / 53 (7.55%)
occurrences (all)	1	3	4
Psychiatric disorders			
Irritability			
subjects affected / exposed	31 / 103 (30.10%)	12 / 52 (23.08%)	11 / 53 (20.75%)
occurrences (all)	31	12	11
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 103 (3.88%)	1 / 52 (1.92%)	4 / 53 (7.55%)
occurrences (all)	4	1	5
Nasopharyngitis			
subjects affected / exposed	29 / 103 (28.16%)	17 / 52 (32.69%)	13 / 53 (24.53%)
occurrences (all)	37	23	18
Pharyngitis			
subjects affected / exposed	1 / 103 (0.97%)	2 / 52 (3.85%)	3 / 53 (5.66%)
occurrences (all)	1	2	4
Rhinitis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 52 (1.92%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	6 / 103 (5.83%)	3 / 52 (5.77%)	0 / 53 (0.00%)
occurrences (all)	7	3	0
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed	29 / 103 (28.16%)	10 / 52 (19.23%)	8 / 53 (15.09%)
occurrences (all)	29	10	8

Non-serious adverse events	Thailand (Group 10):MenACYW Conjugate + MMR+ Varicella Vaccine	Thailand (Group 11): MenACYW Conjugate Vaccine	Thailand (Group 12): MMR + Varicella Vaccine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 86 (60.47%)	33 / 42 (78.57%)	34 / 42 (80.95%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	8 / 86 (9.30%)	7 / 42 (16.67%)	7 / 42 (16.67%)
occurrences (all)	8	7	7
General disorders and administration site conditions			
Crying			
subjects affected / exposed	15 / 86 (17.44%)	14 / 42 (33.33%)	12 / 42 (28.57%)
occurrences (all)	15	14	12
Injection Site Erythema			
subjects affected / exposed	22 / 86 (25.58%)	6 / 42 (14.29%)	7 / 42 (16.67%)
occurrences (all)	51	6	12
Injection Site Pain			
subjects affected / exposed	26 / 86 (30.23%)	15 / 42 (35.71%)	18 / 42 (42.86%)
occurrences (all)	57	15	30
Injection Site Swelling			
subjects affected / exposed	15 / 86 (17.44%)	5 / 42 (11.90%)	4 / 42 (9.52%)
occurrences (all)	35	5	7
Pyrexia			
subjects affected / exposed	6 / 86 (6.98%)	3 / 42 (7.14%)	4 / 42 (9.52%)
occurrences (all)	6	3	4
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 86 (1.16%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	6 / 86 (6.98%)	4 / 42 (9.52%)	6 / 42 (14.29%)
occurrences (all)	6	4	6
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	14 / 86 (16.28%)	11 / 42 (26.19%)	14 / 42 (33.33%)
occurrences (all)	15	11	14
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 42 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	5 / 86 (5.81%)	3 / 42 (7.14%)	6 / 42 (14.29%)
occurrences (all)	5	4	7
Pharyngitis			
subjects affected / exposed	2 / 86 (2.33%)	1 / 42 (2.38%)	2 / 42 (4.76%)
occurrences (all)	2	1	2
Rhinitis			
subjects affected / exposed	0 / 86 (0.00%)	0 / 42 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 86 (3.49%)	2 / 42 (4.76%)	4 / 42 (9.52%)
occurrences (all)	3	2	4
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	11 / 86 (12.79%)	12 / 42 (28.57%)	5 / 42 (11.90%)
occurrences (all)	11	12	5

Non-serious adverse events	Groups 1 and10:MenACYW Conjugate Vaccine+MMR+Varic	Groups 2 and 11: MenACYW Conjugate Vaccine	Groups 3 and 12: MMR + Varicella Vaccine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	137 / 189 (72.49%)	76 / 94 (80.85%)	71 / 95 (74.74%)
Nervous system disorders			

Somnolence			
subjects affected / exposed	25 / 189 (13.23%)	15 / 94 (15.96%)	16 / 95 (16.84%)
occurrences (all)	25	15	16
General disorders and administration site conditions			
Crying			
subjects affected / exposed	36 / 189 (19.05%)	23 / 94 (24.47%)	18 / 95 (18.95%)
occurrences (all)	36	23	18
Injection Site Erythema			
subjects affected / exposed	57 / 189 (30.16%)	26 / 94 (27.66%)	15 / 95 (15.79%)
occurrences (all)	111	26	22
Injection Site Pain			
subjects affected / exposed	57 / 189 (30.16%)	30 / 94 (31.91%)	30 / 95 (31.58%)
occurrences (all)	129	30	51
Injection Site Swelling			
subjects affected / exposed	40 / 189 (21.16%)	19 / 94 (20.21%)	7 / 95 (7.37%)
occurrences (all)	70	19	10
Pyrexia			
subjects affected / exposed	27 / 189 (14.29%)	14 / 94 (14.89%)	14 / 95 (14.74%)
occurrences (all)	27	15	16
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 189 (2.12%)	2 / 94 (2.13%)	0 / 95 (0.00%)
occurrences (all)	4	2	0
Vomiting			
subjects affected / exposed	13 / 189 (6.88%)	7 / 94 (7.45%)	8 / 95 (8.42%)
occurrences (all)	13	7	8
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 189 (1.59%)	0 / 94 (0.00%)	5 / 95 (5.26%)
occurrences (all)	3	0	5
Rhinorrhoea			
subjects affected / exposed	1 / 189 (0.53%)	3 / 94 (3.19%)	4 / 95 (4.21%)
occurrences (all)	1	3	4
Psychiatric disorders			
Irritability			

subjects affected / exposed	45 / 189 (23.81%)	23 / 94 (24.47%)	25 / 95 (26.32%)
occurrences (all)	46	23	25
Infections and infestations			
Bronchitis			
subjects affected / exposed	5 / 189 (2.65%)	1 / 94 (1.06%)	5 / 95 (5.26%)
occurrences (all)	5	1	6
Nasopharyngitis			
subjects affected / exposed	34 / 189 (17.99%)	20 / 94 (21.28%)	19 / 95 (20.00%)
occurrences (all)	42	27	25
Pharyngitis			
subjects affected / exposed	3 / 189 (1.59%)	3 / 94 (3.19%)	5 / 95 (5.26%)
occurrences (all)	3	3	6
Rhinitis			
subjects affected / exposed	0 / 189 (0.00%)	1 / 94 (1.06%)	1 / 95 (1.05%)
occurrences (all)	0	1	1
Upper Respiratory Tract Infection			
subjects affected / exposed	9 / 189 (4.76%)	5 / 94 (5.32%)	4 / 95 (4.21%)
occurrences (all)	10	5	4
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	40 / 189 (21.16%)	22 / 94 (23.40%)	13 / 95 (13.68%)
occurrences (all)	40	22	13

Non-serious adverse events	Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine	Mexico (Group 5): MenACYW Conjugate Vaccine	Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	142 / 200 (71.00%)	65 / 100 (65.00%)	85 / 100 (85.00%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	31 / 200 (15.50%)	15 / 100 (15.00%)	17 / 100 (17.00%)
occurrences (all)	31	15	17
General disorders and administration site conditions			
Crying			
subjects affected / exposed	46 / 200 (23.00%)	25 / 100 (25.00%)	26 / 100 (26.00%)
occurrences (all)	46	25	26
Injection Site Erythema			

subjects affected / exposed	67 / 200 (33.50%)	15 / 100 (15.00%)	37 / 100 (37.00%)
occurrences (all)	96	15	37
Injection Site Pain			
subjects affected / exposed	87 / 200 (43.50%)	27 / 100 (27.00%)	54 / 100 (54.00%)
occurrences (all)	148	27	54
Injection Site Swelling			
subjects affected / exposed	52 / 200 (26.00%)	8 / 100 (8.00%)	30 / 100 (30.00%)
occurrences (all)	68	8	30
Pyrexia			
subjects affected / exposed	35 / 200 (17.50%)	8 / 100 (8.00%)	17 / 100 (17.00%)
occurrences (all)	35	8	17
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	12 / 200 (6.00%)	5 / 100 (5.00%)	6 / 100 (6.00%)
occurrences (all)	13	6	6
Vomiting			
subjects affected / exposed	16 / 200 (8.00%)	7 / 100 (7.00%)	9 / 100 (9.00%)
occurrences (all)	17	7	9
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 200 (2.50%)	3 / 100 (3.00%)	2 / 100 (2.00%)
occurrences (all)	5	3	2
Rhinorrhoea			
subjects affected / exposed	1 / 200 (0.50%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Psychiatric disorders			
Irritability			
subjects affected / exposed	64 / 200 (32.00%)	34 / 100 (34.00%)	33 / 100 (33.00%)
occurrences (all)	64	34	33
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	29 / 200 (14.50%)	18 / 100 (18.00%)	15 / 100 (15.00%)
occurrences (all)	31	18	16

Pharyngitis			
subjects affected / exposed	9 / 200 (4.50%)	6 / 100 (6.00%)	4 / 100 (4.00%)
occurrences (all)	9	6	4
Rhinitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	6 / 200 (3.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	6	1	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	51 / 200 (25.50%)	25 / 100 (25.00%)	20 / 100 (20.00%)
occurrences (all)	51	25	20

Non-serious adverse events	Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine	Russian Federation (Group 8): MenACYW Conjugate Vaccine	Russian Federation (Group 9): PCV13 Vaccine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	75 / 200 (37.50%)	30 / 100 (30.00%)	17 / 99 (17.17%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	25 / 200 (12.50%)	6 / 100 (6.00%)	4 / 99 (4.04%)
occurrences (all)	25	6	4
General disorders and administration site conditions			
Crying			
subjects affected / exposed	8 / 200 (4.00%)	4 / 100 (4.00%)	2 / 99 (2.02%)
occurrences (all)	8	4	2
Injection Site Erythema			
subjects affected / exposed	55 / 200 (27.50%)	17 / 100 (17.00%)	8 / 99 (8.08%)
occurrences (all)	91	17	8
Injection Site Pain			
subjects affected / exposed	37 / 200 (18.50%)	8 / 100 (8.00%)	9 / 99 (9.09%)
occurrences (all)	62	8	9
Injection Site Swelling			
subjects affected / exposed	21 / 200 (10.50%)	7 / 100 (7.00%)	2 / 99 (2.02%)
occurrences (all)	27	7	2
Pyrexia			

subjects affected / exposed	13 / 200 (6.50%)	3 / 100 (3.00%)	2 / 99 (2.02%)
occurrences (all)	13	3	3
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 200 (0.00%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 200 (0.50%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	26 / 200 (13.00%)	16 / 100 (16.00%)	9 / 99 (9.09%)
occurrences (all)	26	16	9
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 100 (0.00%)	1 / 99 (1.01%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	2 / 200 (1.00%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	2	1	0
Pharyngitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	3 / 200 (1.50%)	6 / 100 (6.00%)	1 / 99 (1.01%)
occurrences (all)	3	6	1
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	19 / 200 (9.50%) 19	12 / 100 (12.00%) 12	7 / 99 (7.07%) 7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 July 2016	Following amendment changes were made: Identified the Coordinating Investigator for each country, provided available Health Authority file numbers and update of Regional Clinical Trial Manager information; revised to anticipate the need to potentially include additional sites in South Korea; Visit 0 including activities performed were added for subjects in the Russian Federation; primary endpoint measurement was changed so that it was measured by hSBA instead of rSBA and the definition of hSBA in the primary objective was updated; included screening criteria for the subjects in the Russian Federation; neurological examinations were added according to the recommendations of Russian Health Authorities; updated the planned trial calendar; provided specific labeling information; and updated wording so that Abs to diphtheria, inactivated polio, hepatitis B and Haemophilus influenzae antigens would not be measured before vaccination.
05 May 2017	Following amendment changes were made: Updated to expand the age range of toddlers in Russia who were eligible to receive the 3rd dose of PCV13 vaccine as part of the Russian National Immunization program; specified for pertussis antigens; clarified timing of the 2nd dose of PCV13; included hepatitis B Ab level threshold of 100 mIU/mL for reliable prediction of long-term protection against hepatitis B virus; clarified that only tetanus and pertussis antigens would be tested before and 30 days after vaccination; and defined the end of the trail period as when the last assay results were available and updated trial calendar.
11 September 2017	Following amendment changes were made: Updated protocol to include Thailand as well as information pertaining to Thailand (including but not limited to Principal Investigators, number of sites, number of subjects planned to be enrolled, age of subjects, reporting requirements for SAEs in Thailand) as the study would also be conducted there; updated the number of subjects planned to be enrolled in South Korea; clarified the number of subjects in each group that would have the Ab responses to the meningococcal serogroups A, C, Y, and W measured by rSBA for the observational objective; specified the serostatus cutoffs for Abs to the antigens contained in MMR vaccine and Varicella vaccine based on the assays that were to be used for the analysis;and updated the definition of pertussis vaccine response specific for the booster vaccination response in order to make the definition specific to the manner the vaccine was being used in the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported