Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Catch-up Vaccination Regimens of V114 in Healthy Infants, Children, and Adolescents (PNEU-PLAN)

Summary

EudraCT number	2018-003706-88
Trial protocol	FI PL Outside EU/EEA
Global end of trial date	09 December 2020

Results information

Result version number	v1 (current)
This version publication date	20 June 2021
First version publication date	20 June 2021

Trial information

Trial identification

Sponsor protocol code	V114-024

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03885934
WHO universal trial number (UTN)	-
Other trial identifiers	Study Acronym: PNEU-PLAN

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002215-PIP01-17
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 December 2020
Global end of trial reached?	Yes
Global end of trial date	09 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is 1) to evaluate the safety and tolerability of V114 with respect to the proportion of participants with adverse events (AEs) and 2) to evaluate the anti-pneumococcal polysaccharide (PnPs) serotype-specific Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) at 30 days following the last dose for each vaccination group. There is no formal hypothesis testing in this study.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 June 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 167
Country: Number of subjects enrolled	Malaysia: 65
Country: Number of subjects enrolled	Poland: 94
Country: Number of subjects enrolled	Russian Federation: 19
Country: Number of subjects enrolled	Thailand: 261
Worldwide total number of subjects	606
EEA total number of subjects	261

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)	254
Children (2-11 years)	288

Adolescents (12-17 years)	64
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of approximately 600 participants were planned for enrollment. Randomization was stratified by age and pneumococcal conjugate vaccine (PCV) history.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	V114, Schedule A: Participants 7-11 months

Arm description:

Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.

Arm type	Experimental
Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

V114 15-valent pneumococcal conjugate vaccine (PCV) containing 13 serotypes present in Prevnar 13® (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) and 2 unique serotypes (22F and 33F) in each 0.5 mL IM administration

Arm title	Prevnar 13®, Schedule A: Participants 7-11 months

Arm description:

Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.

Arm type	Active comparator
Investigational medicinal product name	Prevnar 13®
Investigational medicinal product code	
Other name	PCV13
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Prevnar 13® 13-valent PCV containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in each 0.5 mL IM administration.

Arm title	V114, Schedule B: Participants 12-23 months

Arm description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

Arm type	Experimental

Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

V114 15-valent PCV containing 13 serotypes present in Prevnar 13® (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) and 2 unique serotypes (22F and 33F) in each 0.5 mL IM administration

Arm title	Prevnar 13®, Schedule B: Participants 12-23 months

Arm description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

Arm type	Active comparator
Investigational medicinal product name	Prevnar 13®
Investigational medicinal product code	
Other name	PCV13
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Prevnar 13® 13-valent PCV containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in each 0.5 mL IM administration.

Arm title	V114, Schedule C: Participants 2-17 years

Arm description:

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced) (1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

Arm type	Experimental
Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

V114 15-valent PCV containing 13 serotypes present in Prevnar 13® (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) and 2 unique serotypes (22F and 33F) in each 0.5 mL IM administration

Arm title	Prevnar 13®, Schedule C: Participants 2-17 years

Arm description:

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced)(1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

Arm type	Active comparator
Investigational medicinal product name	Prevnar 13®
Investigational medicinal product code	
Other name	PCV13
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Prevnar 13® 13-valent PCV containing 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in each 0.5 mL IM administration.

Number of subjects in period 1	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months	V114, Schedule B: Participants 12-23 months
Started	64	64	62
PCV Dose 1	64	64	62
PCV Dose 2	63	64	62
PCV Dose 3	63	64	0 [1]
Completed	63	64	62
Not completed	1	0	0
Withdrawn by Parent/Guardian	1	-	-

Number of subjects in period 1	Prevnar 13®, Schedule B: Participants 12-23 months	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years
Started	64	177	175
PCV Dose 1	64	177	175
PCV Dose 2	64	0 [2]	0 [3]
PCV Dose 3	0 [4]	0 [5]	0 [6]
Completed	64	177	175
Not completed	0	0	0
Withdrawn by Parent/Guardian	-	-	-

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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

[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: Schedule A: 7 to 11 months received 3 doses; Schedule B: 12-23 months received 2 doses; and Schedule C: 2-17 years received 1 dose.

Baseline characteristics

Reporting groups	
Reporting group title	V114, Schedule A: Participants 7-11 months
Reporting group description:	
Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.	
Reporting group title	Prevnar 13®, Schedule A: Participants 7-11 months
Reporting group description:	
Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.	
Reporting group title	V114, Schedule B: Participants 12-23 months
Reporting group description:	
Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.	
Reporting group title	Prevnar 13®, Schedule B: Participants 12-23 months
Reporting group description:	
Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.	
Reporting group title	V114, Schedule C: Participants 2-17 years
Reporting group description:	
Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced) (1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.	
Reporting group title	Prevnar 13®, Schedule C: Participants 2-17 years
Reporting group description:	
Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced)(1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.	

Reporting group values	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months	V114, Schedule B: Participants 12-23 months
Number of subjects	64	64	62
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	0	0	0
standard deviation	± 0	± 0	± 0

Gender Categorical Units: Subjects			
Female	29	33	30
Male	35	31	32
Race Units: Subjects			
Asian	53	53	52
Multiple	0	0	0
White	11	11	10
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	64	64	62
Not Reported	0	0	0
Age Continuous Units: Months			
arithmetic mean	8.6	8.8	17.7
standard deviation	± 1.4	± 1.6	± 3.2

Reporting group values	Prevnar 13®, Schedule B: Participants 12-23 months	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years
Number of subjects	64	177	175
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	0	6.5	6.5
standard deviation	± 0	± 4.7	± 4.7
Gender Categorical Units: Subjects			
Female	38	85	83
Male	26	92	92
Race Units: Subjects			
Asian	53	60	56
Multiple	0	0	1
White	11	117	118
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0

Not Hispanic or Latino	63	176	174
Not Reported	0	1	1

Age Continuous			
Units: Months			
arithmetic mean	17.8	0	0
standard deviation	± 3.3	± 0	± 0

Reporting group values	Total		
Number of subjects	606		
Age Categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical			
Units: Subjects			
Female	298		
Male	308		
Race			
Units: Subjects			
Asian	327		
Multiple	1		
White	278		
Ethnicity			
Units: Subjects			
Hispanic or Latino	1		
Not Hispanic or Latino	603		
Not Reported	2		
Age Continuous			
Units: Months			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	V114, Schedule A: Participants 7-11 months
Reporting group description:	
Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.	
Reporting group title	Prevnar 13®, Schedule A: Participants 7-11 months
Reporting group description:	
Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve)(3 doses). Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.	
Reporting group title	V114, Schedule B: Participants 12-23 months
Reporting group description:	
Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.	
Reporting group title	Prevnar 13®, Schedule B: Participants 12-23 months
Reporting group description:	
Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve)(2 doses). Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.	
Reporting group title	V114, Schedule C: Participants 2-17 years
Reporting group description:	
Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced) (1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.	
Reporting group title	Prevnar 13®, Schedule C: Participants 2-17 years
Reporting group description:	
Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced)(1 dose). Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.	

Primary: Geometric Mean Concentration of Serotype-specific Immunoglobulin G - Schedule A: 7-11 Months

End point title	Geometric Mean Concentration of Serotype-specific Immunoglobulin G - Schedule A: 7-11 Months[1][2]
End point description:	
The geometric mean concentration (GMC) of immunoglobulin G (IgG) serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13®; and two serotypes (22F and 33F) which are unique to V114 was determined. Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using pneumococcal electrochemiluminescence (PnECL). The 95% CIs were derived by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.	
End point type	Primary
End point timeframe:	
30 days post last 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11

months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=60,59)	2.47 (2.09 to 2.92)	3.66 (2.98 to 4.50)		
Serotype 3 (n=60,59)	2.65 (2.30 to 3.05)	1.71 (1.40 to 2.08)		
Serotype 4 (n=60,59)	2.21 (1.82 to 2.68)	3.85 (3.12 to 4.76)		
Serotype 5 (n=60,59)	3.82 (3.14 to 4.63)	4.56 (3.58 to 5.80)		
Serotype 6A (n=60,59)	2.23 (1.71 to 2.91)	4.30 (3.28 to 5.65)		
Serotype 6B (n=60,59)	3.03 (2.41 to 3.82)	4.17 (3.25 to 5.36)		
Serotype 7F (n=60,59)	5.16 (4.27 to 6.23)	6.42 (5.25 to 7.85)		
Serotype 9V (n=60,59)	2.61 (2.09 to 3.26)	3.59 (2.86 to 4.51)		
Serotype 14 (n=60,59)	9.62 (7.94 to 11.67)	13.07 (10.40 to 16.42)		
Serotype 18C (n=60,59)	3.45 (2.80 to 4.24)	3.50 (2.75 to 4.45)		
Serotype 19A (n=60,59)	4.59 (3.95 to 5.33)	5.81 (4.92 to 6.85)		
Serotype 19F (n=60,59)	3.49 (2.94 to 4.15)	4.83 (4.03 to 5.79)		
Serotype 23F (n=60,59)	2.62 (2.02 to 3.39)	2.79 (2.10 to 3.69)		
Serotype 22F (n=60,58)	9.04 (7.48 to 10.93)	0.14 (0.10 to 0.19)		
Serotype 33F (n=60,59)	3.37 (2.78 to 4.10)	0.13 (0.10 to 0.16)		

Statistical analyses

No statistical analyses for this end point

Primary: GMC of Serotype-specific IgG - Schedule B: 12-23 Months

End point title	GMC of Serotype-specific IgG - Schedule B: 12-23 Months[3][4]

End point description:

The geometric mean concentration of IgG serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13®; and two serotypes (22F and 33F) which are unique to V114 was determined. Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using pneumococcal electrochemiluminescence (PnECL). The 95% CIs were derived by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The analysis population included all randomized

participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

End point type	Primary

End point timeframe:

30 days post last 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule B: Participants 12-23 months	Prevnar 13®, Schedule B: Participants 12-23 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	64		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=56,60)	3.83 (3.07 to 4.77)	4.20 (3.30 to 5.34)		
Serotype 3 (n=56,60)	2.96 (2.44 to 3.58)	1.68 (1.29 to 2.20)		
Serotype 4 (n=56,60)	3.46 (2.67 to 4.50)	4.89 (3.76 to 6.36)		
Serotype 5 (n=56,60)	3.39 (2.65 to 4.34)	3.12 (2.52 to 3.88)		
Serotype 6A (n=56,60)	2.05 (1.30 to 3.23)	3.73 (2.64 to 5.29)		
Serotype 6B (n=56,60)	2.69 (1.70 to 4.25)	2.87 (1.92 to 4.30)		
Serotype 7F (n=56,60)	4.80 (3.63 to 6.34)	5.42 (4.30 to 6.82)		
Serotype 9V (n=56,60)	2.48 (1.97 to 3.11)	2.89 (2.21 to 3.78)		
Serotype 14 (n=56,60)	8.23 (6.19 to 10.94)	8.30 (6.56 to 10.51)		
Serotype 18C (n=56,60)	5.09 (3.98 to 6.52)	3.68 (2.85 to 4.75)		
Serotype 19A (n=56,60)	6.74 (5.29 to 8.60)	5.87 (4.85 to 7.11)		
Serotype 19F (n=56,60)	5.90 (4.69 to 7.43)	5.92 (4.93 to 7.11)		
Serotype 23F (n=56,60)	2.85 (1.99 to 4.07)	2.18 (1.54 to 3.07)		
Serotype 22F (n=56,60)	15.90 (12.16 to 20.78)	0.12 (0.09 to 0.16)		
Serotype 33F (n=56,60)	5.17 (3.96 to 6.74)	0.15 (0.12 to 0.19)		

Statistical analyses

No statistical analyses for this end point

Primary: GMC of Serotype-specific IgG - Schedule C: 2-17 Years

End point title	GMC of Serotype-specific IgG - Schedule C: 2-17 Years[5][6]

End point description:

The geometric mean concentration of IgG serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13®; and two serotypes (22F and 33F) which are unique to V114 was determined. Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using pneumococcal electrochemiluminescence (PnECL). The 95% CIs were derived by exponentiating the CIs of the mean of the natural log values based on the t-distribution. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

End point type	Primary

End point timeframe:

30 days 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	175		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=162,162)	3.00 (2.60 to 3.46)	3.99 (3.48 to 4.58)		
Serotype 3 (n=162,162)	1.37 (1.19 to 1.58)	1.03 (0.88 to 1.21)		
Serotype 4 (n=162,162)	2.53 (2.17 to 2.96)	5.22 (4.52 to 6.03)		
Serotype 5 (n=162,162)	3.43 (2.89 to 4.07)	4.24 (3.46 to 5.20)		
Serotype 6A (n=162,162)	9.03 (7.07 to 11.53)	8.81 (6.96 to 11.14)		
Serotype 6B (n=162,161)	13.55 (10.52 to 17.46)	10.51 (8.01 to 13.78)		
Serotype 7F (n=162,162)	4.03 (3.46 to 4.70)	4.63 (3.92 to 5.46)		
Serotype 9V (n=162,162)	3.60 (3.06 to 4.24)	4.35 (3.65 to 5.20)		
Serotype 14 (n=162,162)	9.21 (7.11 to 11.92)	8.04 (6.24 to 10.36)		
Serotype 18C (n=162,162)	7.16 (6.03 to 8.52)	4.46 (3.76 to 5.30)		
Serotype 19A (n=162,162)	10.99 (9.12 to 13.26)	14.90 (12.23 to 18.16)		
Serotype 19F (n=162,162)	8.95 (7.45 to 10.76)	12.28 (10.07 to 14.97)		
Serotype 23F (n=162,162)	5.36 (4.41 to 6.50)	5.12 (4.12 to 6.37)		

Serotype 22F (n=162,159)	14.99 (12.73 to 17.66)	0.31 (0.24 to 0.38)		
Serotype 33F (n=162,160)	4.89 (4.12 to 5.80)	0.27 (0.22 to 0.32)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Solicited Injection-site Adverse Events - Schedule A: 7-11 Months

End point title	Percentage of Participants with Solicited Injection-site Adverse Events - Schedule A: 7-11 Months[7][8]

End point description:

An adverse event (AE) is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any vaccination report card (VRC)-prompted injection-site AEs that occurred in the 14 days after any vaccination. The percentage of participants with an injection-site AE prompted on the VRC (redness/erythema, hardness/induration, swelling, and pain) was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to Day 14 post any 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: Percentage of Participants				
number (confidence interval 95%)				
Redness/erythema	28.1 (17.6 to 40.8)	34.4 (22.9 to 47.3)		
Hardness/induration	17.2 (8.9 to 28.7)	14.1 (6.6 to 25.0)		
Pain	18.8 (10.1 to 30.5)	7.8 (2.6 to 17.3)		
Swelling	18.8 (10.1 to 30.5)	15.6 (7.8 to 26.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Solicited Injection-site AEs - Schedule B: 12-23 Months

End point title	Percentage of Participants with Solicited Injection-site AEs - Schedule B: 12-23 Months[9][10]

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any vaccination report card (VRC)-prompted injection-site AEs that occurred in the 14 days after any vaccination. The percentage of participants with an injection-site AE prompted on the VRC (redness/erythema, hardness/induration, swelling, and pain) was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to 14 days post any vaccination

Notes:

[9] - 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule B: Participants 12-23 months	Prevnar 13®, Schedule B: Participants 12-23 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	64		
Units: Percentage of Participants				
number (confidence interval 95%)				
Redness/erythema	21.0 (11.7 to 33.2)	21.9 (12.5 to 34.0)		
Hardness/induration	8.1 (2.7 to 17.8)	9.4 (3.5 to 19.3)		
Pain	33.9 (22.3 to 47.0)	23.4 (13.8 to 35.7)		
Swelling	14.5 (6.9 to 25.8)	12.5 (5.6 to 23.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Solicited Injection-site AEs - Schedule C: 2-17 Years

End point title	Percentage of Participants with Solicited Injection-site AEs - Schedule C: 2-17 Years[11][12]

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the

presence of any vaccination report card (VRC)-prompted injection-site AEs that occurred in the 14 days after any vaccination. The percentage of participants with an injection-site AE prompted on the VRC (redness/erythema, hardness/induration, swelling, and pain) was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to 14 days post vaccination

Notes:

[11] - 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	175		
Units: Percentage of Participants				
number (confidence interval 95%)				
Redness/erythema	19.2 (13.7 to 25.8)	21.1 (15.3 to 27.9)		
Hardness/induration	6.8 (3.6 to 11.5)	14.9 (9.9 to 21.0)		
Pain	54.8 (47.2 to 62.3)	56.6 (48.9 to 64.0)		
Swelling	20.9 (15.2 to 27.6)	24.0 (17.9 to 31.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Solicited Systemic AEs - Schedule A: 7-11 Months

End point title	Percentage of Participants With Solicited Systemic AEs - Schedule A: 7-11 Months[13][14]

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any VRC-prompted systemic AEs that occurred in the 14 days after any vaccination. For participants 7 months to <3 years of age at enrollment, solicited systemic AEs include irritability, drowsiness/somnolence, appetite lost/decreased appetite, and hives or welts/urticaria. The percentage of participants with a systemic AE was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to Day 14 post any vaccination

Notes:

[13] - 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: Percentage of Participants				
number (confidence interval 95%)				
Decreased appetite	15.6 (7.8 to 26.9)	18.8 (10.1 to 30.5)		
Irritability	32.8 (21.6 to 45.7)	43.8 (31.4 to 56.7)		
Drowsiness/Somnolence	21.9 (12.5 to 34.0)	15.6 (7.8 to 26.9)		
Hives or Welts/Urticaria	1.6 (0.0 to 8.4)	4.7 (1.0 to 13.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Solicited Systemic AEs - Schedule B: 12-23 Months

End point title	Percentage of Participants With Solicited Systemic AEs - Schedule B: 12-23 Months[15][16]

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any VRC-prompted systemic AEs that occurred in the 14 days after any vaccination. For participants 7 months to <3 years of age at enrollment, solicited systemic AEs include irritability, drowsiness/somnolence, appetite lost/decreased appetite, and hives or welts/urticaria. The percentage of participants with a systemic AE was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to 14 days post any vaccination

Notes:

[15] - 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: No statistical analyses were planned or conducted for this endpoint.

[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: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule B: Participants 12-23 months	Prevnar 13®, Schedule B: Participants 12-23 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	64		
Units: Percentage of Participants				
number (confidence interval 95%)				
Decreased appetite	22.6 (12.9 to 35.0)	18.8 (10.1 to 30.5)		
Irritability	35.5 (23.7 to 48.7)	21.9 (12.5 to 34.0)		
Drowsiness/Somnolence	24.2 (14.2 to 36.7)	17.2 (8.9 to 28.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Solicited Systemic AEs - Schedule C: 2-17 Years

End point title	Percentage of Participants With Solicited Systemic AEs - Schedule C: 2-17 Years[17][18]

End point description:

An AE is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of study vaccine or a protocol-specified procedure, whether or not considered related to the study vaccine or protocol-specified procedure. The parent/guardian of the participant recorded the presence of any VRC-prompted systemic AEs that occurred in the 14 days after any vaccination. For participants 7 months to <3 years of age at enrollment, solicited systemic AEs include irritability, drowsiness/somnolence, appetite lost/decreased appetite, and hives or welts/urticaria. For participants ≥3 years to of age at enrollment, solicited systemic AEs include muscle pain/ myalgia, joint pain/arthralgia, headache, tiredness/fatigue, and hives or welts/urticaria. The percentage of participants with a systemic AE was summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to 14 days post vaccination

Notes:

[17] - 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: No statistical analyses were planned or conducted for this endpoint.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	175		
Units: Percentage of Participants				
number (confidence interval 95%)				
Joint pain/arthralgia	0.0 (0.0 to 2.1)	1.7 (0.4 to 4.9)		

Decreased Appetite	2.3 (0.6 to 5.7)	2.9 (0.9 to 6.5)		
Tiredness/Fatigue	15.8 (10.8 to 22.0)	17.1 (11.9 to 23.6)		
Headache	11.9 (7.5 to 17.6)	13.7 (9.0 to 19.7)		
Irritability	2.8 (0.9 to 6.5)	4.0 (1.6 to 8.1)		
Muscle pain/Myalgia	23.7 (17.7 to 30.7)	16.6 (11.4 to 22.9)		
Sleepiness/Somnolence	2.8 (0.9 to 6.5)	2.9 (0.9 to 6.5)		
Hives or Welts/Urticaria	1.1 (0.1 to 4.0)	1.1 (0.1 to 4.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With at Least 1 Vaccine-related Serious Adverse Event - Schedule A: 7-11 Months

End point title	Percentage of Participants With at Least 1 Vaccine-related Serious Adverse Event - Schedule A: 7-11 Months[19][20]

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that, at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is another important medical event. SAEs that are reported to be at least possibly related by the investigator to study vaccination will be summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to ~6 months post final vaccination

Notes:

[19] - 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: No statistical analyses were planned or conducted for this endpoint.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 5.6)	0.0 (0.0 to 5.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule B: 12-23 Months

End point title	Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule B: 12-23 Months[21][22]

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that, at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is another important medical event. SAEs that are reported to be at least possibly related by the investigator to study vaccination will be summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to ~6 months post final vaccination

Notes:

[21] - 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: No statistical analyses were planned or conducted for this endpoint.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule B: Participants 12-23 months	Prevnar 13®, Schedule B: Participants 12-23 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	64		
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 5.8)	0.0 (0.0 to 5.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule C: 2-17 Years

End point title	Percentage of Participants with at Least 1 Vaccine-related SAE - Schedule C: 2-17 Years[23][24]

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that, at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is another important medical event. SAEs that are reported to be at least possibly related by the investigator to study vaccination will be summarized. The analysis population included all randomized participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to ~6 months post vaccination

Notes:

[23] - 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: No statistical analyses were planned or conducted for this endpoint.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	175		
Units: Percentage of Participants				
number (confidence interval 95%)	0.0 (0.0 to 2.1)	0.0 (0.0 to 2.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting Serotype-specific IgG Threshold Value of ≥0.35 µg/mL for Each of the 15 Serotypes - Schedule A: 7-11 Months

End point title	Percentage of Participants Meeting Serotype-specific IgG Threshold Value of ≥0.35 µg/mL for Each of the 15 Serotypes - Schedule A: 7-11 Months[25]

End point description:

Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using PnECL. The percentage that achieved the GMC threshold value of ≥0.35 µg/mL was summarized. Estimated confidence intervals (CIs) are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

End point type	Secondary

End point timeframe:

30 days post final vaccination

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule A: Participants 7-11 months	Prevnar 13®, Schedule A: Participants 7-11 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		

Serotype 3 (n=60,59)	100.0 (94.0 to 100.0)	96.6 (88.3 to 99.6)		
Serotype 4 (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 5 (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 6A (n=60,59)	95.0 (86.1 to 99.0)	98.3 (90.9 to 100.0)		
Serotype 6B (n=60,59)	96.7 (88.5 to 99.6)	100.0 (93.9 to 100.0)		
Serotype 7F (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 9V (n=60,59)	98.3 (91.1 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 14 (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 18C (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 19A (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 19F (n=60,59)	100.0 (94.0 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 23F (n=60,59)	98.3 (91.1 to 100.0)	100.0 (93.9 to 100.0)		
Serotype 22F (n=60,58)	100.0 (94.0 to 100.0)	13.8 (6.1 to 25.4)		
Serotype 33F (n=60,59)	100.0 (94.0 to 100.0)	11.9 (4.9 to 22.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting Serotype-specific IgG Threshold Value of ≥0.35 µg/mL for Each of the 15 Serotypes - Schedule B: 12-23 Months

End point title	Percentage of Participants Meeting Serotype-specific IgG Threshold Value of ≥0.35 µg/mL for Each of the 15 Serotypes - Schedule B: 12-23 Months[26]

End point description:

Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using PnECL. The percentage that achieved the GMC threshold value of ≥0.35 µg/mL was summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

End point type	Secondary

End point timeframe:

30 days post final vaccination

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule B: Participants 12-23 months	Prevnar 13®, Schedule B: Participants 12-23 months		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	64		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=56,60)	100.0 (93.6 to 100.0)	98.3 (91.1 to 100.0)		
Serotype 3 (n=56,60)	98.2 (90.4 to 100.0)	90.0 (79.5 to 96.2)		
Serotype 4 (n=56,60)	100.0 (93.6 to 100.0)	96.7 (88.5 to 99.6)		
Serotype 5 (n=56,60)	98.2 (90.4 to 100.0)	98.3 (91.1 to 100.0)		
Serotype 6A (n=56,60)	83.9 (71.7 to 92.4)	95.0 (86.1 to 99.0)		
Serotype 6B (n=56,60)	89.3 (78.1 to 96.0)	88.3 (77.4 to 95.2)		
Serotype 7F (n=56,60)	98.2 (90.4 to 100.0)	100.0 (94.0 to 100.0)		
Serotype 9V (n=56,60)	98.2 (90.4 to 100.0)	96.7 (88.5 to 99.6)		
Serotype 14 (n=56,60)	98.2 (90.4 to 100.0)	100.0 (94.0 to 100.0)		
Serotype 18C (n=56,60)	96.4 (87.7 to 99.6)	98.3 (91.1 to 100.0)		
Serotype 19A (n=56,60)	98.2 (90.4 to 100.0)	100.0 (94.0 to 100.0)		
Serotype 19F (n=56,60)	100.0 (93.6 to 100.0)	100.0 (94.0 to 100.0)		
Serotype 23F (n=56,60)	94.6 (85.1 to 98.9)	88.3 (77.4 to 95.2)		
Serotype 22F (n=56,60)	100.0 (93.6 to 100.0)	6.7 (1.8 to 16.2)		
Serotype 33F (n=56,60)	94.6 (85.1 to 98.9)	15.0 (7.1 to 26.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting Serotype-specific IgG Threshold Value of ≥0.35 µg/mL for Each of the 15 Serotypes - Schedule C: 2-17 Years

End point title	Percentage of Participants Meeting Serotype-specific IgG Threshold Value of ≥0.35 µg/mL for Each of the 15 Serotypes - Schedule C: 2-17 Years[27]

End point description:

Sera from participants was used to measure vaccine-induced anti-PnPs serotype-specific IgG for all the 15 serotypes using PnECL. The percentage that achieved the GMC threshold value of ≥0.35 µg/mL was summarized. Estimated CIs are calculated based on the exact binomial method proposed by Clopper and Pearson and are provided in accordance with the statistical analysis plan. The analysis population included all randomized participants without deviations from the protocol that may substantially affect the results of the immunogenicity endpoint.

End point type	Secondary

End point timeframe:

30 days post vaccination

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Each arm of the overall study is identified in successive endpoints (Schedule A: 7-11 months, Schedule B: 12-23 months, and Schedule C: 2-17 years).

End point values	V114, Schedule C: Participants 2-17 years	Prevnar 13®, Schedule C: Participants 2-17 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	175		
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=162,162)	99.4 (96.6 to 100.0)	100.0 (97.7 to 100.0)		
Serotype 3 (n=162,162)	95.7 (91.3 to 98.2)	87.7 (81.6 to 92.3)		
Serotype 4 (n=162,162)	98.8 (95.6 to 99.9)	100.0 (97.7 to 100.0)		
Serotype 5 (n=162,162)	99.4 (96.6 to 100.0)	99.4 (96.6 to 100.0)		
Serotype 6A (n=162,162)	98.1 (94.7 to 99.6)	98.1 (94.7 to 99.6)		
Serotype 6B (n=162,162)	98.1 (94.7 to 99.6)	96.9 (92.9 to 99.0)		
Serotype 7F (n=162,162)	99.4 (96.6 to 100.0)	100.0 (97.7 to 100.0)		
Serotype 9V (n=162,162)	100.0 (97.7 to 100.0)	98.8 (95.6 to 99.9)		
Serotype 14 (n=162,162)	99.4 (96.6 to 100.0)	98.1 (94.7 to 99.6)		
Serotype 18C (n=162,162)	100.0 (97.7 to 100.0)	100.0 (97.7 to 100.0)		
Serotype 19A (n=162,162)	100.0 (97.7 to 100.0)	100.0 (97.7 to 100.0)		
Serotype 19F (n=162,162)	99.4 (96.6 to 100.0)	100.0 (97.7 to 100.0)		
Serotype 23F (n=162,162)	99.4 (96.6 to 100.0)	95.7 (91.3 to 98.2)		
Serotype 22F (n=162,159)	100.0 (97.7 to 100.0)	37.7 (30.2 to 45.8)		
Serotype 33F (n=162,160)	99.4 (96.6 to 100.0)	37.5 (30.0 to 45.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious adverse events: Up to 14 days after vaccination; Serious adverse events and all-cause mortality: Up to ~6 months after the last vaccination.

Adverse event reporting additional description:

The analysis population included all randomized participants who received at least 1 dose of study intervention.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	V114 (7-11 months)

Reporting group description:

Each participant received a 0.5 mL intramuscular (IM) injection for 7 to 11 months of age (Pneumococcal conjugate vaccine [PCV]-naïve). 3 doses. Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.

Reporting group title	Prevnar (7-11 months)

Reporting group description:

Each participant received a 0.5 mL IM injection for 7 to 11 months of age (PCV-naïve). 3 doses. Dose 1: at randomization, Dose 2: 4 to 8 weeks after Dose 1, and Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age.

Reporting group title	V114 (12-23 months)

Reporting group description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve), 2 doses: Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

Reporting group title	Prevnar (12-23 months)

Reporting group description:

Each participant received a 0.5 mL IM injection for 12 to 23 months of age (PCV-naïve), 2 doses: Dose 1: at randomization, and Dose 2: 8 to 12 weeks after Dose 1.

Reporting group title	V114 (2-17 years)

Reporting group description:

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV experienced): Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

Reporting group title	Prevnar (2-17 years)

Reporting group description:

Each participant received a 0.5 mL IM injection for 2 to 17 years of age (PCV-naïve or PCV-experienced): Single dose administered at randomization and at least 8 weeks after previous PCV for participants who were PCV-experienced.

Serious adverse events	V114 (7-11 months)	Prevnar (7-11 months)	V114 (12-23 months)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 64 (10.94%)	5 / 64 (7.81%)	4 / 62 (6.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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	1 / 64 (1.56%)	1 / 64 (1.56%)	0 / 62 (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
Croup infectious			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 64 (3.13%)	0 / 64 (0.00%)	0 / 62 (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
Gastroenteritis salmonella			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	0 / 62 (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
Pharyngitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	0 / 62 (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

Exanthema subitum			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	0 / 62 (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
Tracheobronchitis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	0 / 62 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	0 / 62 (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
Chikungunya virus infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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
Influenza			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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
Wound abscess			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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 / 64 (0.00%)	0 / 64 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	0 / 62 (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 viral			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (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	Prevnar (12-23 months)	V114 (2-17 years)	Prevnar (2-17 years)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 64 (6.25%)	4 / 177 (2.26%)	4 / 175 (2.29%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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

Concussion			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 177 (0.00%)	0 / 175 (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
Croup infectious			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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 / 64 (1.56%)	1 / 177 (0.56%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Pharyngitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 177 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Exanthema subitum			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Tracheobronchitis			

subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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 respiratory syncytial viral			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Chikungunya virus infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Nasopharyngitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 177 (0.00%)	0 / 175 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 64 (1.56%)	0 / 177 (0.00%)	0 / 175 (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
Influenza			
subjects affected / exposed	0 / 64 (0.00%)	1 / 177 (0.56%)	0 / 175 (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
Pneumonia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 177 (0.56%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound abscess			

subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	1 / 175 (0.57%)
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 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Bacteraemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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 viral			
subjects affected / exposed	0 / 64 (0.00%)	0 / 177 (0.00%)	0 / 175 (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
Tuberculosis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 177 (0.56%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	V114 (7-11 months)	Prevnar (7-11 months)	V114 (12-23 months)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 64 (68.75%)	47 / 64 (73.44%)	46 / 62 (74.19%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	14 / 64 (21.88%)	10 / 64 (15.63%)	15 / 62 (24.19%)
occurrences (all)	22	15	29
Headache			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Injection site erythema			
subjects affected / exposed	18 / 64 (28.13%)	22 / 64 (34.38%)	13 / 62 (20.97%)
occurrences (all)	29	36	14
Injection site induration			
subjects affected / exposed	11 / 64 (17.19%)	9 / 64 (14.06%)	5 / 62 (8.06%)
occurrences (all)	20	16	8
Injection site swelling			
subjects affected / exposed	12 / 64 (18.75%)	10 / 64 (15.63%)	9 / 62 (14.52%)
occurrences (all)	23	17	11
Pyrexia			
subjects affected / exposed	20 / 64 (31.25%)	14 / 64 (21.88%)	9 / 62 (14.52%)
occurrences (all)	26	16	11
Injection site pain			
subjects affected / exposed	12 / 64 (18.75%)	5 / 64 (7.81%)	21 / 62 (33.87%)
occurrences (all)	19	6	27
Fatigue			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 64 (6.25%)	3 / 64 (4.69%)	0 / 62 (0.00%)
occurrences (all)	4	3	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	21 / 64 (32.81%)	28 / 64 (43.75%)	22 / 62 (35.48%)
occurrences (all)	39	41	33
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 64 (3.13%)	6 / 64 (9.38%)	8 / 62 (12.90%)
occurrences (all)	2	7	11
Upper respiratory tract infection			

subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	4 / 62 (6.45%)
occurrences (all)	0	0	5
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	10 / 64 (15.63%)	12 / 64 (18.75%)	14 / 62 (22.58%)
occurrences (all)	15	17	21

Non-serious adverse events	Prevnar (12-23 months)	V114 (2-17 years)	Prevnar (2-17 years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 64 (56.25%)	125 / 177 (70.62%)	125 / 175 (71.43%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	11 / 64 (17.19%)	0 / 177 (0.00%)	0 / 175 (0.00%)
occurrences (all)	11	0	0
Headache			
subjects affected / exposed	0 / 64 (0.00%)	21 / 177 (11.86%)	24 / 175 (13.71%)
occurrences (all)	0	32	33
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	14 / 64 (21.88%)	34 / 177 (19.21%)	37 / 175 (21.14%)
occurrences (all)	16	37	37
Injection site induration			
subjects affected / exposed	6 / 64 (9.38%)	12 / 177 (6.78%)	26 / 175 (14.86%)
occurrences (all)	9	13	28
Injection site swelling			
subjects affected / exposed	8 / 64 (12.50%)	37 / 177 (20.90%)	42 / 175 (24.00%)
occurrences (all)	8	39	43
Pyrexia			
subjects affected / exposed	7 / 64 (10.94%)	13 / 177 (7.34%)	13 / 175 (7.43%)
occurrences (all)	7	14	14
Injection site pain			
subjects affected / exposed	15 / 64 (23.44%)	97 / 177 (54.80%)	99 / 175 (56.57%)
occurrences (all)	17	111	106
Fatigue			
subjects affected / exposed	0 / 64 (0.00%)	28 / 177 (15.82%)	30 / 175 (17.14%)
occurrences (all)	0	42	38

Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 177 (0.00%) 0	0 / 175 (0.00%) 0
Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	14 / 64 (21.88%) 18	0 / 177 (0.00%) 0	0 / 175 (0.00%) 0
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	42 / 177 (23.73%) 46	30 / 175 (17.14%) 34
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 64 (10.94%) 7 1 / 64 (1.56%) 1	0 / 177 (0.00%) 0 0 / 177 (0.00%) 0	0 / 175 (0.00%) 0 0 / 175 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	12 / 64 (18.75%) 19	0 / 177 (0.00%) 0	0 / 175 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported