Clinical trial results:
A Phase II, Double-Blind, Randomized, Multicenter Trial to Evaluate the Safety, Tolerability, and Immunogenicity of V114 Compared to Prevnar 13™ in Healthy Infants

Summary

EudraCT number	2016-001117-25
Trial protocol	DK ES FI
Global end of trial date	

Results information

Result version number	v1
This version publication date	13 June 2019
First version publication date	13 June 2019

Trial information

Trial identification

Sponsor protocol code	V114-008

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, 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)	No
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	Interim
Date of interim/final analysis	04 October 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 October 2018
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

This study is designed to evaluate the safety, tolerability, and immunogenicity of two different lots of V114 in healthy infants 6 to 12 weeks ≥42 days to ≤90 days) of age. The primary hypothesis of the study is that the proportion of participants receiving V114 who have serotype specific immunoglobulin G (IgG) ≥0.35 mcg/mL for each of pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F at 1 month after Dose 3 is non-inferior to that for recipients of Prevnar 13™.

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	21 March 2017
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	Canada: 95
Country: Number of subjects enrolled	Denmark: 55
Country: Number of subjects enrolled	Finland: 95
Country: Number of subjects enrolled	Israel: 49
Country: Number of subjects enrolled	Spain: 68
Country: Number of subjects enrolled	United States: 689
Worldwide total number of subjects	1051
EEA total number of subjects	218

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)	1051
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: -

Pre-assignment

Screening details:

Healthy male and female infants approximately 2 months of age (between 42 and 90 days old) (inclusive)were enrolled in this study. other inclusion/exclusion criteria applied.

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, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	V114 Lot 1

Arm description:

Infants received a 0.5 mL intramuscular injection of V114 Lot 1 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)

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:

0.5 mL intramuscular injection of V114 Lot 1 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)

Arm title	V114 Lot 2

Arm description:

Infants received a 0.5 mL intramuscular injection of V114 Lot 2 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)

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:

0.5 mL intramuscular injection of V114 Lot 2 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)

Arm title	Prevnar 13™

Arm description:

Infants received a 0.5 mL intramuscular injection of Prevnar 13™ at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)

Arm type	Active comparator

Investigational medicinal product name	Prevnar 13™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection of Prevnar 13™ at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)

Number of subjects in period 1	V114 Lot 1	V114 Lot 2	Prevnar 13™
Started	351	350	350
Vaccination 1	350	347	347
Vaccination 2	333	335	335
Vaccination 3	330	331	332
Vaccination 4	310	306	311
Completed	308	305	308
Not completed	43	45	42
Adverse event, serious fatal	1	-	-
Physician decision	1	6	-
Consent withdrawn by subject	22	17	21
Adverse event, non-fatal	1	1	-
Lost to follow-up	7	8	4
Lack of efficacy	9	12	12
Protocol deviation	2	1	5

Baseline characteristics

Reporting groups	
Reporting group title	V114 Lot 1
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of V114 Lot 1 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Reporting group title	V114 Lot 2
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of V114 Lot 2 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Reporting group title	Prevnar 13™
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of Prevnar 13™ at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	

Reporting group values	V114 Lot 1	V114 Lot 2	Prevnar 13™
Number of subjects	351	350	350
Age Categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	351	350	350
Gender Categorical Units: Subjects			
Female	164	186	173
Male	187	164	177
Ethnicity Units: Subjects			
Hispanic Or Latino	49	36	53
Not Hispanic Or Latino	300	313	294
Not Reported	0	0	2
Unkown	2	1	1

Reporting group values	Total		
Number of subjects	1051		
Age Categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	1051		
Gender Categorical Units: Subjects			
Female	523		
Male	528		
Ethnicity Units: Subjects			
Hispanic Or Latino	138		
Not Hispanic Or Latino	907		
Not Reported	2		
Unkown	4		

End points

End points reporting groups

Reporting group title	V114 Lot 1
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of V114 Lot 1 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Reporting group title	V114 Lot 2
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of V114 Lot 2 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Reporting group title	Prevnar 13™
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of Prevnar 13™ at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Subject analysis set title	V114 Lot 1-Immunogenicity
Subject analysis set type	Per protocol
Subject analysis set description:	
All participants who were not considered as protocol violators and had data available for the endpoint. Violations include but are not limited to: failure to receive the scheduled doses (at least 28 days between doses 1 and 2 and between doses 2 and 3, and dose 4 at 12 months to 15 months of age) of correct clinical material, and lack of valid serology results available from 28 to 42 days following the dose being analyzed.	
Subject analysis set title	V114 Lot 2-Immunogenicity
Subject analysis set type	Per protocol
Subject analysis set description:	
All participants who were not considered as protocol violators and had data available for the endpoint. Violations include but are not limited to: failure to receive the scheduled doses (at least 28 days between doses 1 and 2 and between doses 2 and 3, and dose 4 at 12 months to 15 months of age) of correct clinical material, and lack of valid serology results available from 28 to 42 days following the dose being analyzed.	
Subject analysis set title	Prevnar 13™-Immunogenicity
Subject analysis set type	Per protocol
Subject analysis set description:	
All participants who were not considered as protocol violators and had data available for the endpoint. Violations include but are not limited to: failure to receive the scheduled doses (at least 28 days between doses 1 and 2 and between doses 2 and 3, and dose 4 at 12 months to 15 months of age) of correct clinical material, and lack of valid serology results available from 28 to 42 days following the dose being analyzed.	
Subject analysis set title	V114 Lot 1-Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants that received at least 1 vaccination and had data available for endpoint.	
Subject analysis set title	V114 Lot 2-Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants that received at least 1 vaccination and had data available for endpoint.	
Subject analysis set title	Prevnar 13™-Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants that received at least 1 vaccination and had data available for endpoint.	

Primary: Percentage of Participants Achieving the Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Threshold Value of ≥0.35 µg/mL for the 13 Common Serotypes in V114 and Prevnar 13™: 1 Month Post Vaccination 3

End point title	Percentage of Participants Achieving the Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Threshold Value of ≥0.35 µg/mL for the 13 Common Serotypes in V114 and Prevnar 13™: 1 Month Post Vaccination 3

End point description:

Serotype-specific pneumococcal IgG antibody was measured using the Meso-Scale Discovery (MSD) Pnelectrochemiluminescence assay (Pn ECL). The percentage of participants with serotype-specific IgG ≥0.35 µg/mL was summarized for each serotype.

End point type	Primary

End point timeframe:

1 month post vaccination 3 (Month 5)

End point values	V114 Lot 1-Immunogenicity	V114 Lot 2-Immunogenicity	Prevnar 13™-Immunogenicity	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	278[1]	273[2]	291[3]	
Units: Percentage of Participants				
number (confidence interval 95%)				
Type 1 (n=278; 273; 291)	96.8 (93.94 to 98.51)	97.8 (95.28 to 99.19)	96.9 (94.21 to 98.58)	
Type 3 (n=277; 273; 291)	96.0 (93.01 to 98.00)	94.1 (90.66 to 96.61)	71.8 (66.28 to 76.92)	
Type 4 (n=273; 272; 288)	98.2 (95.78 to 99.40)	97.1 (94.29 to 98.72)	95.1 (91.98 to 97.32)	
Type 5 (n=278; 272; 290)	96.0 (93.03 to 98.01)	96.0 (92.88 to 97.96)	96.6 (93.75 to 98.33)	
Type 6A (n=278; 273; 290)	90.6 (86.60 to 93.80)	95.6 (92.45 to 97.71)	96.2 (93.31 to 98.09)	
Type 6B (n=276; 273; 290)	90.6 (86.50 to 93.75)	92.3 (88.48 to 95.18)	91.4 (87.54 to 94.34)	
Type 7F (n=278; 273; 290)	99.6 (98.01 to 99.99)	99.3 (97.38 to 99.91)	99.0 (97.01 to 99.79)	
Type 9V (n=2778 273; 289)	97.1 (94.41 to 98.75)	97.8 (95.28 to 99.19)	95.8 (92.86 to 97.84)	
Type 14 (n=277; 273; 289)	99.3 (97.42 to 99.91)	97.4 (94.79 to 98.96)	97.2 (94.62 to 98.80)	
Type 18C (n=278; 273; 291)	96.8 (93.94 to 98.51)	98.2 (95.78 to 99.40)	95.5 (92.48 to 97.60)	
Type 19A (n=278; 273; 290)	98.9 (96.88 to 99.78)	98.5 (96.29 to 99.60)	98.6 (96.51 to 99.62)	
Type 19F (n=278; 273; 290)	100.0 (98.68 to 100.00)	98.9 (96.82 to 99.77)	99.7 (98.09 to 99.99)	
Type 23F (n=278; 273; 290)	92.4 (88.68 to 95.26)	94.9 (91.55 to 97.17)	90.7 (86.74 to 93.77)	

Notes:

[1] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[2] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[3] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

Statistical analyses

Statistical analysis title	Type 1: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	3

Notes:

[4] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 3: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	24.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.7
upper limit	30

Notes:

[5] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 4: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	3

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	6.4

Notes:

[6] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 5: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	2.8

Notes:

[7] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 6A: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-1.6

Notes:

[8] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 6B: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	4

Notes:

[9] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 7F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Differences in percentages
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	2.7

Notes:

[10] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 9V: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	4.6

Notes:

[11] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 14: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	4.7

Notes:

[12] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 18C: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	4.7

Notes:

[13] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 19A: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	2.6

Notes:

[14] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 19F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1.9

Notes:

[15] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 23F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 1 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	non-inferiority[16]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	1.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	6.5

Notes:

[16] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 1: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[17]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	3.9

Notes:

[17] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 3: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	22.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.5
upper limit	28.3

Notes:

[18] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 4: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	5.4

Notes:

[19] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 5: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	2.7

Notes:

[20] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 6A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[21]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	2.8

Notes:

[21] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 6B: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[22]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	5.6

Notes:

[22] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 7F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[23]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	2.4

Notes:

[23] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 9V: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[24]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	5.2

Notes:

[24] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 14: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[25]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	3.1

Notes:

[25] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 18C: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[26]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	2.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	5.9

Notes:

[26] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 19A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[27]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.2

Notes:

[27] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 19F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[28]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	0.9

Notes:

[28] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Statistical analysis title	Type 23F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:	
Difference in Response Rate calculated as Percentage V114 Lot 2 minus Percentage Prevnar 13™	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	8.7

Notes:

[29] - Statistical criterion for non-inferiority corresponds to the lower bound of the adjusted 95% CI of the proportion difference (V114 minus Prevnar 13™) being greater than -0.15 for each of the 13 shared serotypes.

Primary: Geometric Mean Concentration of Serotype-specific Pneumococcal IgG Antibody for the 13 Common Serotypes in V114 and Prevnar 13™ and the 2 Serotypes Unique to V114: 1 Month Post Vaccination 3

End point title	Geometric Mean Concentration of Serotype-specific Pneumococcal IgG Antibody for the 13 Common Serotypes in V114 and Prevnar 13™ and the 2 Serotypes Unique to V114: 1 Month Post Vaccination 3

End point description:

Serotype-specific pneumococcal IgG antibody will be assayed using the Meso-Scale Discovery (MSD) Pn electrochemiluminescence assay. The geometric mean concentration of serotype-specific IgG will be assessed.

End point type	Primary

End point timeframe:

1 month post Vaccination 3 (Month 5)

End point values	V114 Lot 1-Immunogenicity	V114 Lot 2-Immunogenicity	Prevnar 13™-Immunogenicity	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	278[30]	273[31]	291[32]	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Type 1 (n=278; 273; 291)	1.19 (1.10 to 1.27)	1.37 (1.26 to 1.49)	1.65 (1.50 to 1.82)	
Type 3 (n=277; 273; 291)	1.04 (0.97 to 1.12)	1.02 (0.93 to 1.11)	0.53 (0.48 to 0.58)	
Type 4 (n=273; 272; 288)	1.30 (1.21 to 1.40)	1.27 (1.17 to 1.37)	1.26 (1.14 to 1.38)	
Type 5 (n=278; 272; 290)	1.37 (1.25 to 1.50)	1.45 (1.32 to 1.59)	1.75 (1.58 to 1.94)	
Type 6A (n=278; 273; 290)	1.42 (1.27 to 1.59)	1.48 (1.34 to 1.63)	2.62 (2.35 to 2.92)	

Type 6B (n=276; 273; 290)	1.95 (1.68 to 2.28)	1.71 (1.49 to 1.96)	1.89 (1.64 to 2.18)	
Type 7F (n=278; 273; 290)	2.43 (2.26 to 2.62)	2.42 (2.23 to 2.62)	2.98 (2.72 to 3.26)	
Type 9V (n=278; 273; 289)	1.40 (1.28 to 1.52)	1.70 (1.56 to 1.86)	1.59 (1.44 to 1.76)	
Type 14 (n=277; 273; 289)	5.08 (4.63 to 5.58)	4.78 (4.27 to 5.34)	5.79 (5.11 to 6.55)	
Type 18C (n=278; 273; 291)	1.24 (1.15 to 1.35)	1.65 (1.52 to 1.79)	1.67 (1.52 to 1.82)	
Type 19A (n=278; 273; 290)	1.63 (1.52 to 1.76)	1.64 (1.51 to 1.78)	1.99 (1.83 to 2.18)	
Type 19F (n=278; 273; 290)	2.26 (2.10 to 2.43)	2.33 (2.15 to 2.53)	2.57 (2.38 to 2.78)	
Type 23F (n=278; 273; 290)	1.22 (1.10 to 1.35)	1.47 (1.32 to 1.63)	1.25 (1.11 to 1.40)	
Type 22F (n=278; 273; 291)	4.80 (4.40 to 5.24)	4.18 (3.76 to 4.63)	0.05 (0.05 to 0.06)	
Type 33F (n=278; 273; 289)	1.58 (1.34 to 1.86)	1.51 (1.30 to 1.75)	0.05 (0.04 to 0.05)	

Notes:

[30] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[31] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[32] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

Statistical analyses

Statistical analysis title	GMC Ratio-Type 1: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on analysis of variance (ANOVA) model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.81

Statistical analysis title	GMC Ratio-Type 3: Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.75
upper limit	2.23

Statistical analysis title	GMC Ratio-Type 4: Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.16

Statistical analysis title	GMC Ratio-Type 5: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.89

Statistical analysis title	GMC Ratio-Type 6A: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.63

Statistical analysis title	GMC Ratio Type 6B: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.26

Statistical analysis title	GMC Ratio-Type 7F: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.92

Statistical analysis title	GMC Ratio-Type 9V: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1

Statistical analysis title	GMC Ratio-Type 14: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.03

Statistical analysis title	GMC Ratio-Type 18C: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.84

Statistical analysis title	GMC Ratio-Type 19A: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.92

Statistical analysis title	GMC Ratio-Type 23F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.13

Statistical analysis title	GMC Ratio-Type 22F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	92.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	80.84
upper limit	104.81

Statistical analysis title	GMC Ratio-Type 33F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	569
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	34.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.5
upper limit	41.54

Statistical analysis title	GMC Ratio-Type 1: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.94

Statistical analysis title	GMC Ratio-Type 3: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.71
upper limit	2.18

Statistical analysis title	GMC Ratio-Type 4: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.14

Statistical analysis title	GMC Ratio-Type 5: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.94

Statistical analysis title	GMC Ratio-Type 6A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.66

Statistical analysis title	GMC Ratio-Type 6B: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.1

Statistical analysis title	GMC Ratio-Type 7F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.91

Statistical analysis title	GMC Ratio-Type 9V: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.22

Statistical analysis title	GMC Ratio-Type 14: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.97

Statistical analysis title	GMC Ratio-Type 18C: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.12

Statistical analysis title	GMC Ratio-Type 19A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.92

Statistical analysis title	GMC Ratio-Type 19F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.01

Statistical analysis title	GMC Ratio-Type 23F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.37

Statistical analysis title	GMC Ratio-Type 22F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	80.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.3
upper limit	91.24

Statistical analysis title	GMC Ratio-Type 33F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	32.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.25
upper limit	39.78

Primary: Percentage of Participants Who Experience at Least 1 Adverse Event	
End point title	Percentage of Participants Who Experience at Least 1 Adverse Event

End point description:

An adverse event (AE) is defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product or protocol-specified procedure, whether or not considered related to the medicinal product or protocol-specified procedure. Any worsening of a preexisting condition that is temporally associated with the use of the Sponsor's product, is also an AE. The percentage of participants with one or more AEs was assessed.

End point type	Primary

End point timeframe:

Up to 1 month post Vaccination 4 (up to 14 months)

End point values	V114 Lot 1-Safety	V114 Lot 2-Safety	Prevnar 13™-Safety	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	350	347	347	
Units: Percentage of Participants				
number (not applicable)	95.4	97.4	95.4	

Statistical analyses

Statistical analysis title	V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

Difference in percentages calculated as V114 Lot 1 minus Prevnar 13™. Confidence intervals based on Miettinen and Nurminen method.

Comparison groups	V114 Lot 1-Safety v Prevnar 13™-Safety
Number of subjects included in analysis	697
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	3.3

Statistical analysis title	V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

Difference in percentages calculated as V114 Lot 2 minus Prevnar 13™. Confidence intervals based on Miettinen and Nurminen method.

Comparison groups	V114 Lot 2-Safety v Prevnar 13™-Safety

Number of subjects included in analysis	694
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	5.1

Primary: Percentage of Participants Who Discontinued From the Study Due to an Adverse Event

End point title	Percentage of Participants Who Discontinued From the Study Due to an Adverse Event

End point description:

The percentage of participants who discontinued the study because of an AE (as defined above) was assessed.

End point type	Primary

End point timeframe:

Up to 1 month post Vaccination 4 (up to 14 months)

End point values	V114 Lot 1-Safety	V114 Lot 2-Safety	Prevnar 13™-Safety	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	350	347	347	
Units: Percentage of participants				
number (not applicable)	0.3	0.3	0.0	

Statistical analyses

Statistical analysis title	V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

Difference in percentages calculated as V114 Lot 1 minus Prevnar 13™. Confidence intervals based on Miettinen and Nurminen method.

Comparison groups	V114 Lot 1-Safety v Prevnar 13™-Safety
Number of subjects included in analysis	697
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Perentages
Point estimate	0.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	1.6

Statistical analysis title	V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

Difference in percentages calculated as V114 Lot 2 minus Prevnar 13™. Confidence intervals based on Miettinen and Nurminen method.

Comparison groups	V114 Lot 2-Safety v Prevnar 13™-Safety
Number of subjects included in analysis	694
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	1.6

Primary: Percentage of Participants with a Solicited Injection-site Adverse Event

End point title	Percentage of Participants with a Solicited Injection-site Adverse Event[33]

End point description:

Injection-site AEs solicited on the Vaccine Report Card were redness, swelling, hard lump, and pain/tenderness. The percentage of participants with 1 or more solicited injection-site AEs was assessed. Data are not available and will be presented at study completion.

End point type	Primary

End point timeframe:

Up to 14 days post any vaccination

Notes:

[33] - 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: Data are not available and will be presented at study completion..

End point values	V114 Lot 1-Safety	V114 Lot 2-Safety	Prevnar 13™-Safety	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[34]	0[35]	0[36]	
Units: Percentage of participants				

Notes:

[34] - Data not available

[35] - Data not available

[36] - Data not available

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with a Solicited Systemic Adverse Event	
End point title	Percentage of Participants with a Solicited Systemic Adverse Event
End point description:	
Systemic AEs solicited on the Vaccine Report Card were fever, irritability, drowsiness, hive/welts, and appetite loss. The percentage of participants with 1 or more solicited systemic AEs was assessed.	
End point type	Primary
End point timeframe:	
Up to 14 days post any vaccination	

End point values	V114 Lot 1-Safety	V114 Lot 2-Safety	Prevnar 13™-Safety	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	350	347	347	
Units: Percentage of Participants				
number (not applicable)	90.3	92.2	89.6	

Statistical analyses

Statistical analysis title	V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
Difference in percentages calculated as V114 Lot 1 minus Prevnar 13™. Confidence intervals based on Miettinen and Nurminen method.	
Comparison groups	V114 Lot 1-Safety v Prevnar 13™-Safety
Number of subjects included in analysis	697
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.772
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	5.2

Statistical analysis title	V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
Difference in percentages calculated as V114 Lot 2 minus Prevnar 13™. Confidence intervals based on Miettinen and Nurminen method.	
Comparison groups	V114 Lot 2-Safety v Prevnar 13™-Safety

Number of subjects included in analysis	694
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.235
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	7

Secondary: Geometric Mean Concentration of Serotype-specific Pneumococcal IgG Antibody for the 13 Common Serotypes in V114 and Prevnar and the 2 Serotypes Unique to V114: Pre-vaccination 4

End point title	Geometric Mean Concentration of Serotype-specific Pneumococcal IgG Antibody for the 13 Common Serotypes in V114 and Prevnar and the 2 Serotypes Unique to V114: Pre-vaccination 4

End point description:

Serotype-specific pneumococcal IgG antibody was assayed using the MSD Pn electrochemiluminescence assay.

End point type	Secondary

End point timeframe:

Before Vaccination 4 (Month 10 to 13)

End point values	V114 Lot 1-Immunogenicity	V114 Lot 2-Immunogenicity	Prevnar 13™-Immunogenicity	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280[37]	283[38]	287[39]	
Units: µg/mL				
arithmetic mean (confidence interval 95%)				
Type 1 (n=280; 283; 287)	0.32 (0.29 to 0.34)	0.35 (0.33 to 0.38)	0.46 (0.43 to 0.50)	
Type 3 (n=280; 283; 287)	0.25 (0.23 to 0.27)	0.26 (0.24 to 0.29)	0.12 (0.11 to 0.14)	
Type 4 (n=280; 283; 287)	0.26 (0.24 to 0.28)	0.26 (0.24 to 0.27)	0.27 (0.25 to 0.29)	
Type 5 (n=280; 283; 287)	0.74 (0.69 to 0.80)	0.74 (0.68 to 0.79)	0.86 (0.80 to 0.92)	
Type 6A (n=280; 283; 287)	0.33 (0.30 to 0.37)	0.38 (0.35 to 0.41)	0.58 (0.54 to 0.64)	
Type 6B (n=280; 283; 287)	0.61 (0.55 to 0.67)	0.56 (0.51 to 0.62)	0.50 (0.46 to 0.55)	
Type 7F (n=280; 283; 287)	0.77 (0.72 to 0.83)	0.81 (0.76 to 0.88)	1.05 (0.98 to 1.12)	
Type 9V (n=280; 283; 287)	0.40 (0.37 to 0.44)	0.41 (0.38 to 0.44)	0.48 (0.44 to 0.52)	

Type 14 (n=280; 283; 287)	1.34 (1.22 to 1.48)	1.24 (1.12 to 1.37)	2.03 (1.83 to 2.24)	
Type 18C (n=280; 283; 287)	0.28 (0.25 to 0.30)	0.41 (0.38 to 0.44)	0.34 (0.32 to 0.37)	
Type 19A (n=280; 283; 287)	0.40 (0.36 to 0.44)	0.41 (0.37 to 0.45)	0.50 (0.45 to 0.55)	
Type 19F (n=280; 283; 287)	0.43 (0.39 to 0.46)	0.47 (0.43 to 0.52)	0.57 (0.52 to 0.63)	
Type 23F (n=280; 283; 287)	0.29 (0.26 to 0.32)	0.37 (0.33 to 0.40)	0.32 (0.28 to 0.36)	
Type 22F (n=280; 283; 287)	1.30 (1.20 to 1.40)	1.23 (1.14 to 1.32)	0.05 (0.04 to 0.05)	
Type 33F (n=280; 283; 286)	1.01 (0.92 to 1.11)	0.95 (0.87 to 1.04)	0.04 (0.04 to 0.04)	

Notes:

[37] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[38] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[39] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

Statistical analyses

Statistical analysis title	GMC Ratio-Type 1: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.76

Statistical analysis title	GMC Ratio-Type 3: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.75
upper limit	2.28

Statistical analysis title	GMC Ratio-Type 4: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.07

Statistical analysis title	GMC Ratio-Type 5: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	0.96

Statistical analysis title	GMC Ratio-Type 6A: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.65

Statistical analysis title	GMC Ratio-Type 6B: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.06
upper limit	1.39

Statistical analysis title	GMC Ratio-Type 7F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.82

Statistical analysis title	GMC Ratio-Type 9V: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.95

Statistical analysis title	GMC Ratio-Type 14: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.76

Statistical analysis title	GMC Ratio-Type 18C: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.9

Statistical analysis title	GMC Ratio-Type 19A: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.91

Statistical analysis title	GMC Ratio-Type 19F: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.85

Statistical analysis title	GMC Ratio-Type 23F: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.07

Statistical analysis title	GMC Ratio-Type 22F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	27.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.64
upper limit	31.4

Statistical analysis title	GMC Ratio-Type 33F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	25.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.61
upper limit	28.92

Statistical analysis title	GMC Ratio-Type 1: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC ratio
Point estimate	0.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.85

Statistical analysis title	GMC Ratio-Type 3: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.84
upper limit	2.39

Statistical analysis title	GMC Ratio-Type 4: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.05

Statistical analysis title	GMC Ratio-Type 5: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.95

Statistical analysis title	GMC Ratio-Type 6A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.74

Statistical analysis title	GMC Ratio-Type 6B: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.28

Statistical analysis title	GMC Ratio-Type 7F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.86

Statistical analysis title	GMC Ratio-Type 9V: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	0.97

Statistical analysis title	GMC Ratio-Type 14: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.7

Statistical analysis title	GMC Ratio-Type 18C: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.34

Statistical analysis title	GMC Ratio-Type 19A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.94

Statistical analysis title	GMC Ratio-Type 19F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.94

Statistical analysis title	GMC Ratio-Type 23F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.35

Statistical analysis title	GMC Ratio-Type 22F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	26.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.31
upper limit	29.68

Statistical analysis title	GMC Ratio-Type 33F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	570
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	24.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.32
upper limit	27.25

Secondary: Geometric Mean Concentration of Serotype-specific Pneumococcal IgG Antibody for the 13 Common Serotypes in V114 and Prevnar and the 2 Serotypes Unique to V114: 1 Month Post Vaccination 4

End point title	Geometric Mean Concentration of Serotype-specific Pneumococcal IgG Antibody for the 13 Common Serotypes in V114 and Prevnar and the 2 Serotypes Unique to V114: 1 Month Post Vaccination 4

End point description:

Serotype-specific pneumococcal IgG antibody was assayed using the MSD Pn electrochemiluminescence assay.

End point type	Secondary

End point timeframe:

1 month post vaccination 4 (Month 11-14)

End point values	V114 Lot 1-Immunogenicity	V114 Lot 2-Immunogenicity	Prevnar 13™-Immunogenicity	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	273[40]	265[41]	277[42]	
Units: µg/mL				
arithmetic mean (confidence interval 95%)				
Type 1 (n=273; 265; 277)	1.75 (1.60 to 1.92)	2.00 (1.84 to 2.19)	2.47 (2.24 to 2.72)	
Type 3 (n=273; 265; 277)	1.12 (1.03 to 1.22)	1.16 (1.06 to 1.26)	0.78 (0.71 to 0.85)	
Type 4 (n=273; 265; 277)	1.66 (1.49 to 1.85)	1.53 (1.37 to 1.70)	1.88 (1.69 to 2.10)	
Type 5 (n=273: 265; 277)	3.43 (3.09 to 3.80)	3.24 (2.94 to 3.57)	4.72 (4.27 to 5.21)	
Type 6A (n=273; 265; 277)	4.97 (4.49 to 5.51)	4.60 (4.21 to 5.04)	6.94 (6.27 to 7.69)	
Type 6B (n=273; 265; 276)	7.38 (6.68 to 8.15)	5.74 (5.24 to 6.28)	6.91 (6.25 to 7.63)	
Type 7F (n=273; 265; 277)	4.25 (3.87 to 4.66)	4.47 (4.07 to 4.91)	6.29 (5.73 to 6.91)	
Type 9V (n=273; 265; 276)	2.43 (2.20 to 2.69)	2.71 (2.47 to 2.96)	3.53 (3.20 to 3.89)	
Type 14 (n=273; 265; 277)	7.29 (6.54 to 8.14)	7.01 (6.30 to 7.80)	8.28 (7.47 to 9.19)	

Type 18C (n=273; 265; 277)	2.75 (2.47 to 3.05)	3.15 (2.88 to 3.45)	2.94 (2.65 to 3.26)	
Type 19A (n=273; 265; 277)	5.80 (5.33 to 6.31)	5.35 (4.89 to 5.87)	6.53 (5.93 to 7.18)	
Type 19F (n=273; 265; 277)	5.29 (4.81 to 5.82)	4.94 (4.53 to 5.39)	5.47 (4.97 to 6.01)	
Type 23F (n=273; 265; 277)	2.52 (2.25 to 2.83)	3.12 (2.82 to 3.44)	3.38 (3.02 to 3.78)	
Type 22F (n=273; 265; 277)	8.60 (7.85 to 9.42)	7.54 (6.91 to 8.23)	0.06 (0.05 to 0.06)	
Type 33F (n=273; 265; 272)	5.02 (4.59 to 5.49)	4.39 (4.06 to 4.73)	0.06 (0.05 to 0.06)	

Notes:

[40] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[41] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

[42] - Includes Per-protocol participants with data for endpoint; n's vary with serotype

Statistical analyses

Statistical analysis title	GMC Ratio-Type 1: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	Prevnar 13™-Immunogenicity v V114 Lot 1-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.81

Statistical analysis title	GMC Ratio-Type 3: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	1.63

Statistical analysis title	GMC Ratio-Type 4: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.02

Statistical analysis title	GMC Ratio-Type 5: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.84

Statistical analysis title	GMC Ratio-Type 6A: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.82

Statistical analysis title	GMC Ratio-Type 6B: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.22

Statistical analysis title	GMC Ratio-Type 7F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.77

Statistical analysis title	GMC Ratio-Type 9V: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.79

Statistical analysis title	GMC Ratio-Type 14: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.02

Statistical analysis title	GMC Ratio-Type 18C: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.08

Statistical analysis title	GMC Ratio-Type 19A: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.01

Statistical analysis title	GMC Ratio-Type 19F: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.1

Statistical analysis title	GMC Ratio-Type 23F: V114 Lot 1 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.87

Statistical analysis title	GMC Ratio-Type 22F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	149.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	130.23
upper limit	172.06

Statistical analysis title	GMC Ratio-Type 33F: V114 Lot 1 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 1/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 1-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	550
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	90.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	79.93
upper limit	102.12

Statistical analysis title	GMC Ratio-Type 1: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.93

Statistical analysis title	GMC Ratio-Type 3: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.31
upper limit	1.68

Statistical analysis title	GMC Ratio-Type 4: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.94

Statistical analysis title	GMC Ratio-Type 5: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.79

Statistical analysis title	GMC Ratio-Type 6A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.76

Statistical analysis title	GMC Ratio-Type 6B: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.95

Statistical analysis title	GMC Ratio-Type 7F: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.81

Statistical analysis title	GMC Ratio-Type 9V: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.88

Statistical analysis title	GMC Ratio-Type 14: V114 Lot 2 versus Prevnar 13™

Statistical analysis description:

IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.

Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.98

Statistical analysis title	GMC Ratio-Type 18C: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.24

Statistical analysis title	GMC Ratio-Type 19A: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.93

Statistical analysis title	GMC Ratio-Type 19F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description: IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.03

Statistical analysis title	GMC Ratio-Type 23F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.08

Statistical analysis title	GMC Ratio-Type 22F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	131.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	114.05
upper limit	151

Statistical analysis title	GMC Ratio-Type 33F: V114 Lot 2 versus Prevnar 13™
Statistical analysis description:	
IgG GMC Ratio (V114 Lot 2/Prevnar 13™) based on ANOVA model with log-transformed IgG antibody responses as response variable and vaccination group as covariate.	
Comparison groups	V114 Lot 2-Immunogenicity v Prevnar 13™-Immunogenicity

Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	GMC Ratio
Point estimate	78.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.82
upper limit	89.36

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to approximately 1-month (28 to 42 days) post Vaccination 4 (up to 15 months)	
Adverse event reporting additional description:	
All enrolled participants that received at least 1 vaccination	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups	
Reporting group title	V114 Lot 1
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of V114 Lot 1 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Reporting group title	Prevnar 13™
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of Prevnar 13™ at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	
Reporting group title	V114 Lot 2
Reporting group description:	
Infants received a 0.5 mL intramuscular injection of V114 Lot 2 at 2, 4, 6, and 12-15 months of age (Study Day 1, Month 2, Month 4, and Month 10-13)	

Serious adverse events	V114 Lot 1	Prevnar 13™	V114 Lot 2
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 350 (5.14%)	15 / 347 (4.32%)	19 / 347 (5.48%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Concussion			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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
Skull fracture			

subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fontanelle bulging			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Infantile spasms			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum sickness			

subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Infantile colic			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoplakia oral			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Pylorospasm			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Vomiting			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Testicular atrophy			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
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			
Apparent life threatening event			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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 aspiration			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
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 distress			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Purpura			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
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	2 / 350 (0.57%)	1 / 347 (0.29%)	2 / 347 (0.58%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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	2 / 350 (0.57%)	2 / 347 (0.58%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Haemophilus bacteraemia			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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
Otitis media			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Otitis media acute			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Periorbital cellulitis			

subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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
Peritonitis			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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 / 350 (0.00%)	3 / 347 (0.86%)	0 / 347 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	0 / 347 (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
Salmonellosis			
subjects affected / exposed	0 / 350 (0.00%)	0 / 347 (0.00%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 350 (0.00%)	1 / 347 (0.29%)	0 / 347 (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
Viral infection			
subjects affected / exposed	0 / 350 (0.00%)	2 / 347 (0.58%)	1 / 347 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	1 / 350 (0.29%)	0 / 347 (0.00%)	2 / 347 (0.58%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
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 Lot 1	Prevnar 13™	V114 Lot 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	332 / 350 (94.86%)	329 / 347 (94.81%)	336 / 347 (96.83%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	221 / 350 (63.14%)	233 / 347 (67.15%)	241 / 347 (69.45%)
occurrences (all)	564	573	661
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	132 / 350 (37.71%)	128 / 347 (36.89%)	143 / 347 (41.21%)
occurrences (all)	233	221	249
Injection site induration			
subjects affected / exposed	117 / 350 (33.43%)	113 / 347 (32.56%)	109 / 347 (31.41%)
occurrences (all)	206	200	195
Injection site pain			
subjects affected / exposed	198 / 350 (56.57%)	162 / 347 (46.69%)	200 / 347 (57.64%)
occurrences (all)	385	327	393
Injection site swelling			
subjects affected / exposed	98 / 350 (28.00%)	91 / 347 (26.22%)	100 / 347 (28.82%)
occurrences (all)	157	142	176
Pyrexia			
subjects affected / exposed	115 / 350 (32.86%)	141 / 347 (40.63%)	128 / 347 (36.89%)
occurrences (all)	199	252	221
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	39 / 350 (11.14%)	52 / 347 (14.99%)	44 / 347 (12.68%)
occurrences (all)	54	59	61
Teething			
subjects affected / exposed	17 / 350 (4.86%)	19 / 347 (5.48%)	26 / 347 (7.49%)
occurrences (all)	23	22	38

Vomiting			
subjects affected / exposed	27 / 350 (7.71%)	34 / 347 (9.80%)	23 / 347 (6.63%)
occurrences (all)	31	45	24
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	26 / 350 (7.43%)	19 / 347 (5.48%)	19 / 347 (5.48%)
occurrences (all)	31	19	23
Nasal congestion			
subjects affected / exposed	21 / 350 (6.00%)	9 / 347 (2.59%)	15 / 347 (4.32%)
occurrences (all)	28	10	15
Rhinorrhoea			
subjects affected / exposed	15 / 350 (4.29%)	16 / 347 (4.61%)	21 / 347 (6.05%)
occurrences (all)	16	16	29
Psychiatric disorders			
Irritability			
subjects affected / exposed	295 / 350 (84.29%)	294 / 347 (84.73%)	301 / 347 (86.74%)
occurrences (all)	1118	1113	1255
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	25 / 350 (7.14%)	19 / 347 (5.48%)	20 / 347 (5.76%)
occurrences (all)	27	22	23
Otitis media			
subjects affected / exposed	16 / 350 (4.57%)	18 / 347 (5.19%)	16 / 347 (4.61%)
occurrences (all)	16	18	16
Upper respiratory tract infection			
subjects affected / exposed	26 / 350 (7.43%)	34 / 347 (9.80%)	24 / 347 (6.92%)
occurrences (all)	27	42	29
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	158 / 350 (45.14%)	154 / 347 (44.38%)	175 / 347 (50.43%)
occurrences (all)	303	289	331

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 May 2018	Amendment 1: Primary reason for the amendment was to remove the exploratory biomarker section. Other changes included removing 2 non-pertinent immunogenicity outcomes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported