Clinical trial results:
Characterization of the Prevnar Infant Long-Term Immune Response Versus a Prevnar-Naive Cohort

Summary

EudraCT number	2014-004158-32
Trial protocol	Outside EU/EEA
Global end of trial date	10 May 2010

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	01 August 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-3016

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00824850
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851014

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 June 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 May 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the "late" immune response to an additional dose of pneumococcal conjugate vaccine more than 10 years after primary vaccination with 7-valent pneumococcal conjugate vaccine (7vPnC) in infancy versus a 7vPnC-naive cohort, to evaluate kinetics of secondary immune responses in order to measure serotype-specific anti-pneumococcal immunoglobulin G (IgG) and OPA titer and to evaluate the safety profile of 13-valent pneumococcal conjugate vaccine (13vPnC) as measured by the rate of serious adverse events (SAEs), adverse events (AEs), and solicited local reactions and systemic events in the 2 groups.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 January 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 75
Worldwide total number of subjects	75
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	11
Adolescents (12-17 years)	64
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were previously enrolled in Prevnar protocol D118-P8 (study duration 1995 to 1998) and were randomized to receive either 7vPnC or meningococcal C conjugate vaccine (MnCC) in that study.

Pre-assignment

Screening details:

A total of 75 subjects were screened in two sites of United States. Study was started on 26 January 2010 and completed on 10 May 2010.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	7vPnC / 13vPnC

Arm description:

13vPnC administered as a single dose. Subjects had previously received 7vPnC in study D118-P8.

Arm type	Experimental
Investigational medicinal product name	7-valent pneumococcal conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects had previously received 7vPnC in study D118-P8.

Investigational medicinal product name	13-valent Pneumococcal Conjugate Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered with 13vPnC as a single 0.5 milliliter (mL) dose intramuscularly (IM).

Arm title	MnCC / 13vPnC

Arm description:

13vPnC administered as a single dose. Subjects had previously received MnCC in study D118-P8.

Arm type	Experimental
Investigational medicinal product name	Meningococcal C conjugate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects had previously received MnCC in study D118-P8.

Investigational medicinal product name	13-valent Pneumococcal Conjugate Vaccine
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered with 13vPnC as a single 0.5 mL dose IM.

Number of subjects in period 1	7vPnC / 13vPnC	MnCC / 13vPnC
Started	38	37
Received Vaccination 13vPnC	38	36
Completed	38	36
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups	
Reporting group title	7vPnC / 13vPnC
Reporting group description:	
13vPnC administered as a single dose. Subjects had previously received 7vPnC in study D118-P8.	
Reporting group title	MnCC / 13vPnC
Reporting group description:	
13vPnC administered as a single dose. Subjects had previously received MnCC in study D118-P8.	

Reporting group values	7vPnC / 13vPnC	MnCC / 13vPnC	Total
Number of subjects	38	37	75
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	12.6	13.1	
standard deviation	± 1.1	± 0.9	-
Gender, Male/Female Units: subjects			
Female	15	16	31
Male	23	21	44

End points

End points reporting groups

Reporting group title	7vPnC / 13vPnC
Reporting group description:	
13vPnC administered as a single dose. Subjects had previously received 7vPnC in study D118-P8.	
Reporting group title	MnCC / 13vPnC
Reporting group description:	
13vPnC administered as a single dose. Subjects had previously received MnCC in study D118-P8.	
Subject analysis set title	7vPnC / 13vPnC prevaccination Visit 1
Subject analysis set type	Full analysis
Subject analysis set description:	
13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received 7vPnC in study D118-P8.	
Subject analysis set title	7vPnC / 13vPnC postvaccination Visit 5
Subject analysis set type	Full analysis
Subject analysis set description:	
13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received 7vPnC in study D118-P8.	
Subject analysis set title	MnCC / 13vPnC prevaccination Visit 1
Subject analysis set type	Full analysis
Subject analysis set description:	
13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received MnCC in study D118-P8.	
Subject analysis set title	MnCC / 13vPnC postvaccination Visit 5
Subject analysis set type	Full analysis
Subject analysis set description:	
13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received MnCC in study D118-P8.	
Subject analysis set title	7vPnC / 13vPnC postvaccination Visit 4
Subject analysis set type	Full analysis
Subject analysis set description:	
13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received 7vPnC in study D118-P8.	
Subject analysis set title	MnCC / 13vPnC postvaccination Visit 4
Subject analysis set type	Full analysis
Subject analysis set description:	
13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received MnCC in study D118-P8.	

Primary: Percentage of Subjects Achieving a Pneumococcal IgG Antibody Concentration Greater Than or Equal to (≥) 0.35 Microgram per Milliliter (mcg/mL) for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 5)

End point title	Percentage of Subjects Achieving a Pneumococcal IgG Antibody Concentration Greater Than or Equal to (≥) 0.35 Microgram per Milliliter (mcg/mL) for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 5)

End point description:

Percentage of subjects achieving predefined IgG antibody threshold ≥0.35 mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A) along with the exact, 2-sided 95% confidence intervals (CIs) based on the observed percentage of subjects. Evaluable Immunogenicity population: eligible subjects based on all inclusion and exclusion criteria, had a baseline blood sample collection performed (Visit 1), received 1 dose of 13vPnC, and had Visit 5 blood sample collection performed, and at least 1 valid and determinate assay

result at Visit 1 and also at Visit 5.

End point type	Primary
End point timeframe:	
Day 28 (Visit 5)	

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35		
Units: observed percentage of subjects				
number (confidence interval 95%)				
7vPnC serotype 4	100 (90.7 to 100)	100 (90 to 100)		
7vPnC serotype 6B	100 (90.7 to 100)	100 (90 to 100)		
7vPnC serotype 9V	100 (90.7 to 100)	100 (90 to 100)		
7vPnC serotype 14	100 (90.7 to 100)	97.1 (85.1 to 99.9)		
7vPnC serotype 18C	100 (90.7 to 100)	100 (90 to 100)		
7vPnC serotype 19F	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 23F	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 1	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 3	94.7 (82.3 to 99.4)	97 (84.2 to 99.9)		
Additional serotype 5	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 6A	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 7F	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 19A	100 (90.7 to 100)	100 (90 to 100)		

Statistical analyses

Statistical analysis title	7vPnC serotype 4
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided confidence interval (CI).	
Comparison groups	MnCC / 13vPnC v 7vPnC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[1]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[1] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[2]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[2] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[3]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[3] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[4]
Parameter estimate	Difference in proportions (percentage)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	14.9

Notes:

[4] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[5]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[5] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[6]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[6] - Descriptive

Statistical analysis title	7vPnC serotype 23F
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[7]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[7] - Descriptive

Statistical analysis title	Additional serotype 3
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[8]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.7
upper limit	10.9

Notes:

[8] - Descriptive

Statistical analysis title	Additional serotype 1
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[9]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[9] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[10]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[10] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[11]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[11] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[12]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[12] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[13]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[13] - Descriptive

Primary: Percentage of Subjects Achieving a Pneumococcal IgG Antibody Concentration ≥0.35 Mcg/mL for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 4)

End point title	Percentage of Subjects Achieving a Pneumococcal IgG Antibody Concentration ≥0.35 Mcg/mL for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 4)

End point description:

Percentage of subjects achieving predefined IgG antibody threshold ≥0.35 mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A) along with the exact, 2-sided 95% CIs based on the observed percentage of subjects. Evaluable Immunogenicity population.

End point type	Primary

End point timeframe:

Day 7 (Visit 4)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38[14]	35[15]		
Units: observed percentage of subjects				
number (confidence interval 95%)				
7vPnC serotype 4	94.7 (82.3 to 99.4)	85.7 (69.7 to 95.2)		
7vPnC serotype 6B	100 (90.7 to 100)	100 (90 to 100)		
7vPnC serotype 9V	100 (90.7 to 100)	97.1 (85.1 to 99.9)		
7vPnC serotype 14	100 (90.7 to 100)	94.3 (80.8 to 99.3)		
7vPnC serotype 18C	97.4 (86.2 to 99.9)	94.3 (80.8 to 99.3)		
7vPnC serotype 19F	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 23F	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 1	100 (90.7 to 100)	97.1 (85.1 to 99.9)		
Additional serotype 3	94.7 (82.3 to 99.4)	87.9 (71.8 to 96.6)		
Additional serotype 5	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 6A	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 7F	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 19A	100 (90.7 to 100)	100 (90 to 100)		

Notes:

[14] - Number of subjects with a determinate IgG antibody concentration for the serotypes.

[15] - Number of subjects with a determinate IgG antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[16]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[16] - Descriptive

Statistical analysis title	7vPnC serotype 4
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[17]
Parameter estimate	Difference in proportions (percentage)
Point estimate	9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	25.5

Notes:

[17] - Descriptive

Statistical analysis title	7vPnC serotype 9V
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[18]
Parameter estimate	Difference in proportions (percentage)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	14.9

Notes:

[18] - Descriptive

Statistical analysis title	7vPnC serotype 14
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[19]
Parameter estimate	Difference in proportions (percentage)
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	19.2

Notes:

[19] - Descriptive

Statistical analysis title	7vPnC serotype 19F
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[20]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[20] - Descriptive

Statistical analysis title	7vPnC serotype 18C
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[21]
Parameter estimate	Difference in proportions (percentage)
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	17

Notes:

[21] - Descriptive

Statistical analysis title	7vPnC serotype 23F
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[22]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[22] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[23]
Parameter estimate	Difference in proportions (percentage)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	14.9

Notes:

[23] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[24]
Parameter estimate	Difference in proportions (percentage)
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	23.4

Notes:

[24] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[25]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[25] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[26]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[26] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[27]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[27] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[28]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[28] - Descriptive

Primary: Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥Lower Limit of Quantification (LLOQ) for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 5)

End point title	Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥Lower Limit of Quantification (LLOQ) for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 5)

End point description:

Percentage of subjects achieving predefined OPA antibody titer ≥serotype-specific LLOQ using modified microcolony assays for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A) along with the exact, 2-sided 95% CIs based on the observed percentage of subjects. LLOQ for each serotype: 1=1:8, 3=1:12, 4=1:21, 5=1:29, 6A=1:37, 6B=1:43, 7F=1:210, 9V=1:345, 14=1:35, 18C=1:31, 19A=1:18, 19F=1:48, 23F=1:13. Evaluable Immunogenicity population.

End point type	Primary

End point timeframe:

Day 28 (Visit 5)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38[29]	35[30]		
Units: observed percentage of subjects				
number (confidence interval 95%)				
7vPnC serotype 4	100 (90.3 to 100)	100 (89.1 to 100)		
7vPnC serotype 6B	100 (90.5 to 100)	100 (90 to 100)		
7vPnC serotype 9V	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 14	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 18C	100 (90.7 to 100)	100 (90 to 100)		

7vPnC serotype 19F	97.4 (86.2 to 99.9)	100 (89.7 to 100)		
7vPnC serotype 23F	100 (90.5 to 100)	100 (90 to 100)		
Additional serotype 1	100 (90.7 to 100)	97.1 (84.7 to 99.9)		
Additional serotype 3	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 5	89.5 (75.2 to 97.1)	88.6 (73.3 to 96.8)		
Additional serotype 6A	100 (90.7 to 100)	100 (89.7 to 100)		
Additional serotype 7F	100 (90.5 to 100)	100 (90 to 100)		
Additional serotype 19A	97.4 (86.2 to 99.9)	100 (90 to 100)		

Notes:

[29] - Number of subjects with a determinate OPA antibody titer to the serotypes.

[30] - Number of subjects with a determinate OPA antibody titer to the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[31]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	10.9

Notes:

[31] - Descriptive

Statistical analysis title	7vPnC serotype 6B
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[32]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[32] - Descriptive

Statistical analysis title	7vPnC serotype 9V
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[33]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[33] - Descriptive

Statistical analysis title	7vPnC serotype 14
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[34]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[34] - Descriptive

Statistical analysis title	7vPnC serotype 18C
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[35]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[35] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[36]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	8

Notes:

[36] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[37]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[37] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[38]
Parameter estimate	Difference in proportions (percentage)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	15.3

Notes:

[38] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[39]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[39] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[40]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15
upper limit	17.6

Notes:

[40] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[41]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[41] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[42]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[42] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[43]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	7.6

Notes:
[43] - Descriptive

Primary: Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥LLOQ for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 4)

End point title	Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥LLOQ for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 4)

End point description:

Percentage of subjects achieving predefined OPA antibody titer ≥serotype-specific LLOQ using modified microcolony assays for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A) along with the exact, 2-sided 95% CIs based on the observed percentage of subjects. LLOQ for each serotype: 1=1:8, 3=1:12, 4=1:21, 5=1:29, 6A=1:37, 6B=1:43, 7F=1:210, 9V=1:345, 14=1:35, 18C=1:31, 19A=1:18, 19F=1:48, 23F=1:13. Evaluable Immunogenicity population.

End point type	Primary

End point timeframe:

Day 7 (Visit 4)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38[44]	35[45]		
Units: observed percentage of subjects				
number (confidence interval 95%)				
7vPnC serotype 4	97.4 (86.2 to 99.9)	100 (89.7 to 100)		
7vPnC serotype 6B	100 (90.7 to 100)	100 (89.4 to 100)		
7vPnC serotype 9V	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 14	100 (90.5 to 100)	100 (89.7 to 100)		
7vPnC serotype 18C	100 (90.5 to 100)	100 (90 to 100)		
7vPnC serotype 19F	94.3 (80.8 to 99.3)	97.1 (84.7 to 99.9)		
7vPnC serotype 23F	97.3 (85.8 to 99.9)	94.3 (80.8 to 99.3)		
Additional serotype 1	100 (90.5 to 100)	97.1 (85.1 to 99.9)		
Additional serotype 3	97.4 (86.2 to 99.9)	100 (89.7 to 100)		
Additional serotype 5	89.5 (75.2 to 97.1)	88.2 (72.5 to 96.7)		
Additional serotype 6A	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 7F	100 (90.5 to 100)	97 (84.2 to 99.9)		
Additional serotype 19A	97.4 (86.2 to 99.9)	100 (90 to 100)		

Notes:

[44] - Number of subjects with a determinate OPA antibody titer to the serotypes.

[45] - Number of subjects with a determinate OPA antibody titer to the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[46]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	8

Notes:

[46] - Descriptive

Statistical analysis title	7vPnC serotype 6B
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[47]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	10.6

Notes:

[47] - Descriptive

Statistical analysis title	7vPnC serotype 9V
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[48]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[48] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[49]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10.3

Notes:

[49] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[50]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.8
upper limit	10.1

Notes:

[50] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[51]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[51] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[52]
Parameter estimate	Difference in proportions (percentage)
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	16.6

Notes:

[52] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[53]
Parameter estimate	Difference in proportions (percentage)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	15

Notes:

[53] - Descriptive

Statistical analysis title	Additional serotype 3
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[54]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	8

Notes:

[54] - Descriptive

Statistical analysis title	Additional serotype 5
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[55]
Parameter estimate	Difference in proportions (percentage)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.8
upper limit	18.2

Notes:

[55] - Descriptive

Statistical analysis title	Additional serotype 6A
Statistical analysis description:	
Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[56]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[56] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[57]
Parameter estimate	Difference in proportions (percentage)
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	15.8

Notes:

[57] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

Difference in proportions, [7vPnC / 13vPnC) - (MnCC / 13vPnC), expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[58]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	7.6

Notes:

[58] - Descriptive

Primary: Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥1:8 for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 5)

End point title	Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥1:8 for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 5)

End point description:

Percentage of subjects achieving predefined OPA antibody titer ≥1:8 for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A) along with the exact, 2-sided 95% CIs based on the observed percentage of subjects. The lowest titer that can be determined using the standard OPA assay is a titer of 1:8 limit of detection (LOD) and was the same for each serotype-specific OPA assay. Evaluable Immunogenicity population.

End point type	Primary

End point timeframe:

Day 28 (Visit 5)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35[59]		
Units: observed percentage of subjects				
number (confidence interval 95%)				
7vPnC serotype 4	100 (90.3 to 100)	100 (89.1 to 100)		
7vPnC serotype 6B	100 (90.5 to 100)	100 (90 to 100)		
7vPnC serotype 9V	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 14	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 18C	100 (90.7 to 100)	100 (90 to 100)		
7vPnC serotype 19F	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 23F	100 (90.5 to 100)	100 (90 to 100)		
Additional serotype 1	100 (90.7 to 100)	100 (89.7 to 100)		
Additional serotype 3	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 5	97.4 (86.2 to 99.9)	94.3 (80.8 to 99.3)		
Additional serotype 6A	100 (90.7 to 100)	100 (89.7 to 100)		
Additional serotype 7F	100 (90.5 to 100)	100 (90 to 100)		
Additional serotype 19A	100 (90.7 to 100)	100 (90 to 100)		

Notes:

[59] - Subjects with a determinate OPA antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[60]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	10.9

Notes:

[60] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[61]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[61] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[62]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[62] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[63]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[63] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[64]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[64] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[65]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[65] - Descriptive

Statistical analysis title	7vPnC serotype 23F
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[66]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[66] - Descriptive

Statistical analysis title	Additional serotype 3
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[67]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[67] - Descriptive

Statistical analysis title	Additional serotype 1
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[68]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[68] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[69]
Parameter estimate	Difference in proportions (percentage)
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	17

Notes:

[69] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[70]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[70] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[71]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[71] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[72]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[72] - Descriptive

Primary: Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥1:8 for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 4)

End point title	Percentage of Subjects Achieving a Pneumococcal Opsonophagocytic Activity (OPA) Antibody Titer ≥1:8 for the 13 Serotypes for 7vPnC / 13vPnC in Comparison to MnCC / 13vPnC After Vaccination (Visit 4)

End point description:

Percentage of subjects achieving predefined OPA antibody titer ≥1:8 for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A) along with the exact, 2-sided 95% CIs based on the observed percentage of subjects. The lowest titer that can be determined using the standard OPA assay is a titer of 1:8 LOD and was the same for each serotype-specific OPA assay. Evaluable Immunogenicity population.

End point type	Primary

End point timeframe:

Day 7 (Visit 4)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35[73]		
Units: observed percentage of subjects				
number (confidence interval 95%)				
7vPnC serotype 4	97.4 (86.2 to 99.9)	100 (89.7 to 100)		
7vPnC serotype 6B	100 (90.7 to 100)	100 (89.4 to 100)		
7vPnC serotype 9V	100 (90.7 to 100)	100 (89.7 to 100)		
7vPnC serotype 14	100 (90.5 to 100)	100 (89.7 to 100)		
7vPnC serotype 18C	100 (90.5 to 100)	100 (90 to 100)		
7vPnC serotype 19F	100 (90 to 100)	100 (89.7 to 100)		
7vPnC serotype 23F	97.3 (85.8 to 99.9)	94.3 (80.8 to 99.3)		
Additional serotype 1	100 (90.5 to 100)	100 (90 to 100)		
Additional serotype 3	100 (90.7 to 100)	100 (89.7 to 100)		
Additional serotype 5	97.4 (86.2 to 99.9)	94.1 (80.3 to 99.3)		
Additional serotype 6A	100 (90.7 to 100)	100 (90 to 100)		
Additional serotype 7F	100 (90.5 to 100)	100 (89.4 to 100)		
Additional serotype 19A	100 (90.7 to 100)	100 (90 to 100)		

Notes:

[73] - Subjects with a determinate OPA antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[74]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	10.6

Notes:

[74] - Descriptive

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[75]
Parameter estimate	Difference in proportions (percentage)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	8

Notes:

[75] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[76]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[76] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[77]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10.3

Notes:

[77] - Descriptive

Statistical analysis title	7vPnC serotype 9V
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[78]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[78] - Descriptive

Statistical analysis title	7vPnC serotype 19F
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[79]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	10.5

Notes:

[79] - Descriptive

Statistical analysis title	Additional serotype 1
Statistical analysis description:	
Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[80]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	10.1

Notes:

[80] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[81]
Parameter estimate	Difference in proportions (percentage)
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	16.6

Notes:

[81] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[82]
Parameter estimate	Difference in proportions (percentage)
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.6
upper limit	17.2

Notes:

[82] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[83]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	10.3

Notes:

[83] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[84]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[84] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[85]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	10.6

Notes:

[85] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

Difference in proportions, [(7vPnC/13vPnC) – (MnCC/13vPnC)], expressed as a percentage, along with exact 2-sided CI.

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[86]
Parameter estimate	Difference in proportions (percentage)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	10

Notes:

[86] - Descriptive

Secondary: Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point title	Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point description:

Pneumococcal IgG GMCs measured as mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMCs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMCs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 28 (Visit 5)

End point values	7vPnC / 13vPnC prevaccination Visit 1	7vPnC / 13vPnC postvaccination Visit 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	38	38		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	0.2 (0.12 to 0.33)	5.96 (4.1 to 8.65)		
7vPnC serotype 6B	5.89 (4.61 to 7.51)	66.72 (50.19 to 88.7)		
7vPnC serotype 9V	1.54 (1.19 to 2)	8.62 (6.55 to 11.34)		
7vPnC serotype 14	0.58 (0.39 to 0.86)	41.45 (27.72 to 61.97)		
7vPnC serotype 18C	0.75 (0.48 to 1.18)	5.93 (4.34 to 8.11)		

7vPnC serotype 19F	2.94 (2.08 to 4.15)	13.41 (8.89 to 20.23)		
7vPnC serotype 23F	2.51 (1.92 to 3.27)	17.2 (12.44 to 23.77)		
Additional serotype 1	1.04 (0.71 to 1.54)	11.59 (7.34 to 18.3)		
Additional serotype 3	1.3 (0.83 to 2.04)	2.19 (1.6 to 2.99)		
Additional serotype 5	3.24 (2.45 to 4.27)	6.8 (4.75 to 9.74)		
Additional serotype 6A	3.78 (2.85 to 5.03)	29.11 (19.04 to 44.5)		
Additional serotype 7F	1.38 (0.93 to 2.05)	9.92 (7.03 to 14.01)		
Additional serotype 19A	7.05 (5.52 to 8.99)	21.29 (14.9 to 30.43)		

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

Geometric mean fold rises (GMFRs) were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[87]
Parameter estimate	geometric mean fold rise
Point estimate	29.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.61
upper limit	49.33

Notes:

[87] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[88]
Parameter estimate	geometric mean fold rise
Point estimate	11.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.49
upper limit	15.13

Notes:

[88] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[89]
Parameter estimate	geometric mean fold rise
Point estimate	5.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.06
upper limit	7.67

Notes:

[89] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[90]
Parameter estimate	geometric mean fold rise
Point estimate	71.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	40.74
upper limit	124.08

Notes:

[90] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[91]
Parameter estimate	geometric mean fold rise
Point estimate	7.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.92
upper limit	12.73

Notes:

[91] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[92]
Parameter estimate	geometric mean fold rise
Point estimate	4.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.87
upper limit	7.26

Notes:

[92] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[93]
Parameter estimate	geometric mean fold rise
Point estimate	6.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.51
upper limit	10.42

Notes:

[93] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[94]
Parameter estimate	geometric mean fold rise
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	2.07

Notes:

[94] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[95]
Parameter estimate	geometric mean fold rise
Point estimate	11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.98
upper limit	17.64

Notes:

[95] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[96]
Parameter estimate	geometric mean fold rise
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.52
upper limit	2.9

Notes:

[96] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[97]
Parameter estimate	geometric mean fold rise
Point estimate	7.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.95
upper limit	10.48

Notes:

[97] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[98]
Parameter estimate	geometric mean fold rise
Point estimate	7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.77
upper limit	12.42

Notes:

[98] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[99]
Parameter estimate	geometric mean fold rise
Point estimate	3.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.23
upper limit	4.1

Notes:

[99] - Descriptive

Secondary: Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations

(GMCs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point title	Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point description:

Pneumococcal IgG GMCs measured as mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMCs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMCs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 28 (Visit 5)

End point values	MnCC / 13vPnC prevaccination Visit 1	MnCC / 13vPnC postvaccination Visit 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	35		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	0.15 (0.07 to 0.29)	2.86 (2 to 4.07)		
7vPnC serotype 6B	3.97 (2.78 to 5.67)	22.62 (14.56 to 35.16)		
7vPnC serotype 9V	1.69 (1.2 to 2.38)	4.7 (3.49 to 6.33)		
7vPnC serotype 14	0.79 (0.43 to 1.43)	18.5 (10.1 to 33.9)		
7vPnC serotype 18C	0.72 (0.46 to 1.13)	9.79 (6.43 to 14.9)		
7vPnC serotype 19F	2.01 (1.32 to 3.05)	18.02 (11.56 to 28.08)		
7vPnC serotype 23F	2.31 (1.7 to 3.14)	20.8 (13.07 to 33.08)		
Additional serotype 1	0.7 (0.43 to 1.15)	5.3 (3.4 to 8.26)		
Additional serotype 3	1.16 (0.73 to 1.86)	1.81 (1.25 to 2.62)		
Additional serotype 5	3.83 (2.77 to 5.31)	7.39 (4.98 to 10.96)		
Additional serotype 6A	3.82 (2.79 to 5.23)	17.05 (10.82 to 26.87)		
Additional serotype 7F	1.12 (0.73 to 1.72)	5.94 (4.08 to 8.65)		
Additional serotype 19A	6.18 (4.57 to 8.35)	20.17 (15.28 to 26.63)		

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[100]
Parameter estimate	geometric mean fold rise
Point estimate	19.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.99
upper limit	38.77

Notes:

[100] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[101]
Parameter estimate	geometric mean fold rise
Point estimate	2.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.16
upper limit	3.57

Notes:

[101] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[102]
Parameter estimate	geometric mean fold rise
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.9
upper limit	8.33

Notes:

[102] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[103]
Parameter estimate	geometric mean fold rise
Point estimate	23.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.17
upper limit	41.79

Notes:

[103] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[104]
Parameter estimate	geometric mean fold rise
Point estimate	13.68

Confidence interval	
level	95 %
sides	2-sided
lower limit	8.94
upper limit	20.92

Notes:

[104] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[105]
Parameter estimate	geometric mean fold rise
Point estimate	8.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.21
upper limit	12.97

Notes:

[105] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[106]
Parameter estimate	geometric mean fold rise
Point estimate	9
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.91
upper limit	13.72

Notes:

[106] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[107]
Parameter estimate	geometric mean fold rise
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	1.86

Notes:

[107] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[108]
Parameter estimate	geometric mean fold rise
Point estimate	7.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.36
upper limit	10.72

Notes:

[108] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[109]
Parameter estimate	geometric mean fold rise
Point estimate	1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.43
upper limit	2.6

Notes:

[109] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[110]
Parameter estimate	geometric mean fold rise
Point estimate	5.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.65
upper limit	7.75

Notes:

[110] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[111]
Parameter estimate	geometric mean fold rise
Point estimate	4.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.09
upper limit	6.45

Notes:

[111] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[112]
Parameter estimate	geometric mean fold rise
Point estimate	3.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.49
upper limit	4.28

Notes:

[112] - Descriptive

Secondary: Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point title	Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point description:

Pneumococcal IgG GMCs measured as mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMCs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMCs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 7 (Visit 4)

End point values	7vPnC / 13vPnC prevaccination Visit 1	7vPnC / 13vPnC postvaccination Visit 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	38	38		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	0.2 (0.12 to 0.33)	3.21 (2.1 to 4.9)		

7vPnC serotype 6B	5.89 (4.61 to 7.51)	29.46 (20.74 to 41.86)		
7vPnC serotype 9V	1.54 (1.19 to 2)	5.96 (4.57 to 7.76)		
7vPnC serotype 14	0.58 (0.39 to 0.86)	10.25 (6.85 to 15.33)		
7vPnC serotype 18C	0.75 (0.48 to 1.18)	3.17 (2.26 to 4.42)		
7vPnC serotype 19F	2.94 (2.08 to 4.15)	7.46 (5.43 to 10.25)		
7vPnC serotype 23F	2.51 (1.92 to 3.27)	10.56 (7.69 to 14.51)		
Additional serotype 1	1.04 (0.71 to 1.54)	4.42 (2.93 to 6.67)		
Additional serotype 3	1.3 (0.83 to 2.04)	2.12 (1.54 to 2.92)		
Additional serotype 5	3.24 (2.45 to 4.27)	5.4 (4.08 to 7.15)		
Additional serotype 6A	3.78 (2.85 to 5.03)	13.6 (9.01 to 20.53)		
Additional serotype 7F	1.38 (0.93 to 2.05)	4.7 (3.26 to 6.78)		
Additional serotype 19A	7.05 (5.52 to 8.99)	13.4 (10.3 to 17.42)		

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[113]
Parameter estimate	geometric mean fold rise
Point estimate	15.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.16
upper limit	27.46

Notes:

[113] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC

	postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[114]
Parameter estimate	geometric mean fold rise
Point estimate	5.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.5
upper limit	7.16

Notes:

[114] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[115]
Parameter estimate	geometric mean fold rise
Point estimate	3.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.93
upper limit	5.09

Notes:

[115] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[116]
Parameter estimate	geometric mean fold rise
Point estimate	17.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.11
upper limit	27.79

Notes:

[116] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[117]
Parameter estimate	geometric mean fold rise
Point estimate	4.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.86
upper limit	6.23

Notes:

[117] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[118]
Parameter estimate	geometric mean fold rise
Point estimate	2.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	3.62

Notes:

[118] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[119]
Parameter estimate	geometric mean fold rise
Point estimate	4.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.86
upper limit	6.19

Notes:

[119] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[120]
Parameter estimate	geometric mean fold rise
Point estimate	1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2.05

Notes:

[120] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[121]
Parameter estimate	geometric mean fold rise
Point estimate	4.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.79
upper limit	6.42

Notes:

[121] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[122]
Parameter estimate	geometric mean fold rise
Point estimate	1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	2.14

Notes:

[122] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[123]
Parameter estimate	geometric mean fold rise
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.39
upper limit	5.42

Notes:

[123] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[124]
Parameter estimate	geometric mean fold rise
Point estimate	3.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.42
upper limit	4.82

Notes:

[124] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[125]
Parameter estimate	geometric mean fold rise
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	2.26

Notes:

[125] - Descriptive

Secondary: Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point title	Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point description:

Pneumococcal IgG GMCs measured as mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMCs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMCs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 7 (Visit 4)

End point values	MnCC / 13vPnC prevaccination Visit 1	MnCC / 13vPnC postvaccination Visit 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35[126]	35[127]		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	0.15 (0.07 to 0.29)	1.21 (0.7 to 2.11)		
7vPnC serotype 6B	3.97 (2.78 to 5.67)	9.42 (6.23 to 14.24)		
7vPnC serotype 9V	1.69 (1.2 to 2.38)	3.41 (2.51 to 4.65)		
7vPnC serotype 14	0.79 (0.43 to 1.43)	5.22 (2.76 to 9.86)		
7vPnC serotype 18C	0.72 (0.46 to 1.13)	3.53 (2.16 to 5.76)		
7vPnC serotype 19F	2.01 (1.32 to 3.05)	5.47 (3.51 to 8.54)		
7vPnC serotype 23F	2.31 (1.7 to 3.14)	6.51 (4.24 to 10.01)		
Additional serotype 1	0.7 (0.43 to 1.15)	2.65 (1.75 to 4)		
Additional serotype 3	1.11 (0.67 to 1.82)	1.46 (0.97 to 2.2)		
Additional serotype 5	3.83 (2.77 to 5.31)	5 (3.49 to 7.15)		
Additional serotype 6A	3.82 (2.79 to 5.23)	7.79 (5.17 to 11.72)		
Additional serotype 7F	1.12 (0.73 to 1.72)	3.21 (2.25 to 4.59)		
Additional serotype 19A	6.18 (4.57 to 8.35)	12.03 (8.83 to 16.39)		

Notes:

[126] - Subjects with valid and determinate assay results for both pre and post vaccination blood draw.

[127] - Subjects with valid and determinate assay results for both pre and post vaccination blood draw.

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[128]
Parameter estimate	geometric mean fold rise
Point estimate	8.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	15.56

Notes:

[128] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[129]
Parameter estimate	geometric mean fold rise
Point estimate	2.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	3.16

Notes:

[129] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[130]
Parameter estimate	geometric mean fold rise
Point estimate	2.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.63
upper limit	2.49

Notes:

[130] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[131]
Parameter estimate	geometric mean fold rise
Point estimate	6.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.31
upper limit	10.15

Notes:

[131] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[132]
Parameter estimate	geometric mean fold rise
Point estimate	4.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.34
upper limit	7.26

Notes:

[132] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[133]
Parameter estimate	geometric mean fold rise
Point estimate	2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.08
upper limit	3.57

Notes:

[133] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[134]
Parameter estimate	geometric mean fold rise
Point estimate	2.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.08
upper limit	3.83

Notes:

[134] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[135]
Parameter estimate	geometric mean fold rise
Point estimate	3.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.8
upper limit	5.13

Notes:

[135] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[136]
Parameter estimate	geometric mean fold rise
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.57

Notes:

[136] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[137]
Parameter estimate	geometric mean fold rise
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	1.61

Notes:

[137] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[138]
Parameter estimate	geometric mean fold rise
Point estimate	2.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	2.75

Notes:

[138] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[139]
Parameter estimate	geometric mean fold rise
Point estimate	2.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.19
upper limit	3.77

Notes:

[139] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[140]
Parameter estimate	geometric mean fold rise
Point estimate	1.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.59
upper limit	2.39

Notes:

[140] - Descriptive

Secondary: Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point title	Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point description:

Antibody geometric mean titers as measured by opsonophagocytic activity (OPA) assay for 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMTs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMTs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 28 (Visit 5)

End point values	7vPnC / 13vPnC prevaccination Visit 1	7vPnC / 13vPnC postvaccination Visit 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	38	38		
Units: Titer				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	22 (6.3 to 80.7)	4535 (2836.5 to 7251.3)		
7vPnC serotype 6B	1024 (488.4 to 2148.4)	11939 (8748.1 to 16293.9)		
7vPnC serotype 9V	43 (13.4 to 137.3)	6709 (5097.5 to 8829.4)		
7vPnC serotype 14	159 (63.7 to 396)	5946 (4361.1 to 8107.6)		
7vPnC serotype 18C	54 (19.5 to 149.5)	5067 (3375.1 to 7607.2)		
7vPnC serotype 19F	33 (15.1 to 73.3)	1623 (995.2 to 2647.9)		
7vPnC serotype 23F	87 (34.1 to 223.4)	2799 (2048.5 to 3823.2)		
Additional serotype 1	6 (4.3 to 7.4)	440 (301.8 to 641.2)		
Additional serotype 3	11 (6.9 to 16.6)	111 (87.1 to 141.1)		
Additional serotype 5	4 (3.6 to 5.6)	277 (145.2 to 526.4)		
Additional serotype 6A	17 (7.1 to 39.7)	9029 (6255 to 13034)		
Additional serotype 7F	60 (17.7 to 205.3)	7036 (4886 to 10131.8)		
Additional serotype 19A	76 (36.7 to 157.5)	1869 (1099.8 to 3177.3)		

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the

mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[141]
Parameter estimate	geometric mean fold rise
Point estimate	201.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.11
upper limit	739.05

Notes:

[141] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[142]
Parameter estimate	geometric mean fold rise
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.2
upper limit	26.1

Notes:

[142] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[143]
Parameter estimate	geometric mean fold rise
Point estimate	156.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	48.72
upper limit	501.86

Notes:

[143] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[144]
Parameter estimate	geometric mean fold rise
Point estimate	37.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.71
upper limit	102.31

Notes:

[144] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[145]
Parameter estimate	geometric mean fold rise
Point estimate	93.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.99
upper limit	284.31

Notes:

[145] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[146]
Parameter estimate	geometric mean fold rise
Point estimate	48.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.27
upper limit	101.97

Notes:

[146] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[147]
Parameter estimate	geometric mean fold rise
Point estimate	32.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.99
upper limit	85.81

Notes:

[147] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[148]
Parameter estimate	geometric mean fold rise
Point estimate	78.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.42
upper limit	120.94

Notes:

[148] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[149]
Parameter estimate	geometric mean fold rise
Point estimate	10.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	15.72

Notes:

[149] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[150]
Parameter estimate	geometric mean fold rise
Point estimate	61.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.75
upper limit	116.34

Notes:

[150] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[151]
Parameter estimate	geometric mean fold rise
Point estimate	536.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	212.04
upper limit	1357.19

Notes:

[151] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[152]
Parameter estimate	geometric mean fold rise
Point estimate	116.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.28
upper limit	410.33

Notes:

[152] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other[153]
Parameter estimate	geometric mean fold rise
Point estimate	24.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.3
upper limit	53.42

Notes:

[153] - Descriptive

Secondary: Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point title	Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 5

End point description:

Antibody geometric mean titers as measured by opsonophagocytic activity (OPA) assay for 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMTs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population; GMTs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 28 (Visit 5)

End point values	MnCC / 13vPnC prevaccination Visit 1	MnCC / 13vPnC postvaccination Visit 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35[154]	35[155]		
Units: Titer				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	28 (4.5 to 174.3)	4704 (2958 to 7481.1)		
7vPnC serotype 6B	288 (74.8 to 1106.9)	11607 (7762.6 to 17354.1)		
7vPnC serotype 9V	120 (37.9 to 382.8)	7457 (5702.3 to 9751.9)		
7vPnC serotype 14	262 (98.1 to 700.5)	7006 (4997.7 to 9822.1)		
7vPnC serotype 18C	25 (8.4 to 75.7)	5736 (4141.4 to 7943.8)		
7vPnC serotype 19F	23 (10.5 to 50.6)	2696 (1831 to 3968.5)		
7vPnC serotype 23F	11 (5 to 23.5)	5197 (3599.2 to 7503.1)		

Additional serotype 1	5 (4 to 6.6)	341 (221.9 to 524.9)		
Additional serotype 3	11 (7 to 18.2)	98 (75.2 to 126.9)		
Additional serotype 5	4 (3.7 to 5)	336 (175.4 to 642.2)		
Additional serotype 6A	24 (8.9 to 64.2)	10488 (7460.6 to 14744.7)		
Additional serotype 7F	76 (21.1 to 275.2)	6098 (4392.9 to 8464.9)		
Additional serotype 19A	39 (19.9 to 78.1)	2424 (1696.6 to 3462.4)		

Notes:

[154] - Subjects with valid and determinate assay results for both the pre and post vaccination blood draw.
[155] - Subjects with valid and determinate assay results for both the pre and post vaccination blood draw.

Statistical analyses

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMRFs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[156]
Parameter estimate	geometric mean fold rise
Point estimate	40.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.97
upper limit	148.44

Notes:

[156] - Descriptive

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[157]
Parameter estimate	geometric mean fold rise
Point estimate	168.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	20.22
upper limit	1409.76

Notes:

[157] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[158]
Parameter estimate	geometric mean fold rise
Point estimate	61.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.83
upper limit	203.72

Notes:

[158] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[159]
Parameter estimate	geometric mean fold rise
Point estimate	26.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.67
upper limit	73.84

Notes:

[159] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[160]
Parameter estimate	geometric mean fold rise
Point estimate	116.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.54
upper limit	250.13

Notes:

[160] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[161]
Parameter estimate	geometric mean fold rise
Point estimate	226.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	79.81
upper limit	645.29

Notes:

[161] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[162]
Parameter estimate	geometric mean fold rise
Point estimate	481
Confidence interval	
level	95 %
sides	2-sided
lower limit	207.01
upper limit	1117.69

Notes:

[162] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[163]
Parameter estimate	geometric mean fold rise
Point estimate	66.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.8
upper limit	105.75

Notes:

[163] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[164]
Parameter estimate	geometric mean fold rise
Point estimate	8.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.36
upper limit	13.94

Notes:

[164] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[165]
Parameter estimate	geometric mean fold rise
Point estimate	78.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.38
upper limit	147.8

Notes:

[165] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[166]
Parameter estimate	geometric mean fold rise
Point estimate	438.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	169.52
upper limit	1132.43

Notes:

[166] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[167]
Parameter estimate	geometric mean fold rise
Point estimate	80
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.28
upper limit	274.82

Notes:

[167] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 5 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 5
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other[168]
Parameter estimate	geometric mean fold rise
Point estimate	61.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.73
upper limit	131.76

Notes:

[168] - Descriptive

Secondary: Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point title	Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to 7vPnC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point description:

Antibody geometric mean titers as measured by opsonophagocytic activity (OPA) assay for 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMTs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMTs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 7 (Visit 4)

End point values	7vPnC / 13vPnC prevaccination Visit 1	7vPnC / 13vPnC postvaccination Visit 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37[169]	37[170]		
Units: Titer				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	19 (6 to 62.8)	5449 (3118.6 to 9519.8)		
7vPnC serotype 6B	1034 (505.1 to 2116.9)	7885 (5792 to 10734)		
7vPnC serotype 9V	43 (13.4 to 137.3)	6497 (4357.4 to 9687.5)		
7vPnC serotype 14	148 (58.2 to 375.7)	3497 (2440.8 to 5009.1)		
7vPnC serotype 18C	58 (20.6 to 163.8)	5922 (3784 to 9268.9)		
7vPnC serotype 19F	40 (17.4 to 91.6)	1243 (620.6 to 2489.8)		
7vPnC serotype 23F	79 (31.4 to 201.3)	1487 (884.7 to 2499.5)		
Additional serotype 1	6 (4.3 to 7.6)	367 (228.8 to 587.3)		
Additional serotype 3	11 (6.9 to 16.6)	119 (82.1 to 172)		
Additional serotype 5	4 (3.6 to 5.6)	185 (100.9 to 337.5)		
Additional serotype 6A	17 (7.1 to 39.7)	8072 (5195.8 to 12538.8)		
Additional serotype 7F	60 (17.7 to 205.3)	4601 (2998.3 to 7060.6)		
Additional serotype 19A	76 (36.7 to 157.5)	1345 (767.4 to 2357.7)		

Notes:

[169] -
Subjects with valid and determinate assay results for both the pre and post vaccination blood draw.
[170] -
Subjects with valid and determinate assay results for both the pre and post vaccination blood draw.

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[171]
Parameter estimate	geometric mean fold rise
Point estimate	281.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	76.65
upper limit	1035.49

Notes:

[171] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[172]
Parameter estimate	geometric mean fold rise
Point estimate	7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.47
upper limit	16.75

Notes:

[172] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[173]
Parameter estimate	geometric mean fold rise
Point estimate	151.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.01
upper limit	545.84

Notes:

[173] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[174]
Parameter estimate	geometric mean fold rise
Point estimate	23.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.67
upper limit	64.54

Notes:

[174] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[175]
Parameter estimate	geometric mean fold rise
Point estimate	102.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	32
upper limit	325.4

Notes:

[175] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[176]
Parameter estimate	geometric mean fold rise
Point estimate	31.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.71
upper limit	76.13

Notes:

[176] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[177]
Parameter estimate	geometric mean fold rise
Point estimate	18.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.82
upper limit	51.39

Notes:

[177] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[178]
Parameter estimate	geometric mean fold rise
Point estimate	64.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.33
upper limit	111.18

Notes:

[178] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[179]
Parameter estimate	geometric mean fold rise
Point estimate	11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.64
upper limit	18.52

Notes:

[179] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[180]
Parameter estimate	geometric mean fold rise
Point estimate	41.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.09
upper limit	73.48

Notes:

[180] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[181]
Parameter estimate	geometric mean fold rise
Point estimate	479.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	171.63
upper limit	1339.96

Notes:

[181] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[182]
Parameter estimate	geometric mean fold rise
Point estimate	76.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.63
upper limit	270.02

Notes:

[182] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CIs for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	7vPnC / 13vPnC prevaccination Visit 1 v 7vPnC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other[183]
Parameter estimate	geometric mean fold rise
Point estimate	17.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.61
upper limit	41.08

Notes:
[183] - Descriptive

Secondary: Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point title	Pneumococcal Opsonophagocytic Activity (OPA) Assay Geometric Mean Titers (GMTs) for the 13 Serotypes Relative to MnCC / 13vPnC Prevaccination Visit 1 and Postvaccination Visit 4

End point description:

Antibody geometric mean titers as measured by opsonophagocytic activity (OPA) assay for 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMTs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMTs calculated using all subjects with available data at both the prevaccination and postvaccination blood draws.

End point type	Secondary

End point timeframe:

Baseline (Visit 1), Day 7 (Visit 4)

End point values	MnCC / 13vPnC prevaccination Visit 1	MnCC / 13vPnC postvaccination Visit 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34[184]	34[185]		
Units: Titer				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	40 (6.3 to 254)	6782 (3687.6 to 12471.3)		
7vPnC serotype 6B	405 (103.5 to 1584.7)	7195 (4585.5 to 11289.8)		
7vPnC serotype 9V	116 (36.8 to 364.9)	7855 (5532.9 to 11152.1)		
7vPnC serotype 14	280 (103.1 to 760.7)	6209 (4253.9 to 9063.3)		
7vPnC serotype 18C	25 (8.4 to 75.7)	5193 (3658.1 to 7372.3)		
7vPnC serotype 19F	20 (9.4 to 44.7)	1855 (1055.8 to 3258.2)		
7vPnC serotype 23F	11 (5 to 23.5)	991 (501.3 to 1959.3)		
Additional serotype 1	5 (4 to 6.5)	385 (249.4 to 595.6)		
Additional serotype 3	12 (7.2 to 19)	101 (72.2 to 141.1)		
Additional serotype 5	4 (3.7 to 5)	258 (132.3 to 503.4)		
Additional serotype 6A	23 (8.7 to 59.1)	6107 (4149.7 to 8987.5)		
Additional serotype 7F	95 (24.7 to 363.8)	3577 (1774.8 to 7208.2)		
Additional serotype 19A	39 (19.9 to 78.1)	1763 (1220.1 to 2547.6)		

Notes:

[184] - Number of subjects with a determinate OPA antibody titer to the serotypes.

[185] - Number of subjects with a determinate OPA antibody titer to the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[186]
Parameter estimate	geometric mean fold rise
Point estimate	170.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.24
upper limit	1301.79

Notes:

[186] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

GMRFs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[187]
Parameter estimate	geometric mean fold rise
Point estimate	17.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.27
upper limit	59.91

Notes:

[187] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[188]
Parameter estimate	geometric mean fold rise
Point estimate	67.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.45
upper limit	249.02

Notes:

[188] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[189]
Parameter estimate	geometric mean fold rise
Point estimate	22.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.94
upper limit	61.88

Notes:

[189] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[190]
Parameter estimate	geometric mean fold rise
Point estimate	205.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.04
upper limit	602.78

Notes:

[190] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[191]
Parameter estimate	geometric mean fold rise
Point estimate	90.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.28
upper limit	203.27

Notes:

[191] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[192]
Parameter estimate	geometric mean fold rise
Point estimate	91.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.25
upper limit	232.13

Notes:

[192] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[193]
Parameter estimate	geometric mean fold rise
Point estimate	75.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.32
upper limit	120.91

Notes:

[193] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[194]
Parameter estimate	geometric mean fold rise
Point estimate	8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.21
upper limit	14.4

Notes:

[194] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4

Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[195]
Parameter estimate	geometric mean fold rise
Point estimate	60
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.06
upper limit	115.92

Notes:

[195] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[196]
Parameter estimate	geometric mean fold rise
Point estimate	37.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.85
upper limit	131.09

Notes:

[196] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC postvaccination Visit 4 v MnCC / 13vPnC prevaccination Visit 1
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[197]
Parameter estimate	geometric mean fold rise
Point estimate	269.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	105.09
upper limit	692.6

Notes:
[197] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

GMFRs were calculated (postvaccination Visit 4 / prevaccination Visit 1) using all subjects with available data from both the prevaccination and postvaccination blood draws. CI for the GMRFs were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the mean fold rise.

Comparison groups	MnCC / 13vPnC prevaccination Visit 1 v MnCC / 13vPnC postvaccination Visit 4
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	other[198]
Parameter estimate	geometric mean fold rise
Point estimate	44.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.31
upper limit	94.01

Notes:
[198] - Descriptive

Secondary: Comparison of Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 5)

End point title	Comparison of Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 5)

End point description:

Pneumococcal IgG GMCs measured as Mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMCs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMCs were calculated using all subjects with available data for the specified blood draw.

End point type	Secondary

End point timeframe:

Day 28 (Visit 5)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35[199]		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	5.73 (4.21 to 7.81)	2.92 (2.22 to 3.83)		
7vPnC serotype 6B	66.72 (50.19 to 88.7)	22.62 (14.56 to 35.16)		

7vPnC serotype 9V	8.72 (6.68 to 11.4)	4.7 (3.49 to 6.33)		
7vPnC serotype 14	41.45 (27.72 to 61.97)	18.5 (10.1 to 33.9)		
7vPnC serotype 18C	5.72 (4.18 to 7.82)	9.04 (5.98 to 13.68)		
7vPnC serotype 19F	14.17 (9.54 to 21.07)	15.8 (10 to 24.96)		
7vPnC serotype 23F	17.2 (12.44 to 23.77)	20.8 (13.07 to 33.08)		
Additional serotype 1	9.55 (6.46 to 14.13)	5.63 (3.67 to 8.64)		
Additional serotype 3	2.13 (1.58 to 2.87)	1.71 (1.2 to 2.44)		
Additional serotype 5	6.8 (4.75 to 9.74)	7.52 (5.12 to 11.04)		
Additional serotype 6A	29.11 (19.04 to 44.5)	16.08 (10.18 to 25.4)		
Additional serotype 7F	9.92 (7.03 to 14.01)	5.75 (3.98 to 8.33)		
Additional serotype 19A	21.29 (14.9 to 30.43)	20.17 (15.28 to 26.63)		

Notes:

[199] - Subjects with a determinate OPA antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4
Statistical analysis description:	
CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[200]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.31
upper limit	2.95

Notes:

[200] - Descriptive

Statistical analysis title	7vPnC serotype 6B
Statistical analysis description:	
CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[201]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	4.9

Notes:

[201] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[202]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	2.75

Notes:

[202] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[203]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	2.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	4.53

Notes:

[203] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[204]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.05

Notes:

[204] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[205]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.62

Notes:

[205] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[206]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.43

Notes:

[206] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[207]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.96

Notes:

[207] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[208]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	3

Notes:

[208] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[209]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.52

Notes:

[209] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[210]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	2.83

Notes:

[210] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[211]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	3.34

Notes:

[211] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[212]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.66

Notes:

[212] - Descriptive

Secondary: Comparison of Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 4)

End point title	Comparison of Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 4)

End point description:

Pneumococcal IgG GMCs measured as Mcg/mL for the 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMCs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMCs were calculated using all subjects with available data for the specified blood draw.

End point type	Secondary

End point timeframe:

Day 7 (Visit 4)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35[213]		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	3 (2.07 to 4.35)	1.37 (0.9 to 2.1)		
7vPnC serotype 6B	29.46 (20.74 to 41.86)	9.42 (6.23 to 14.24)		
7vPnC serotype 9V	5.75 (4.4 to 7.51)	3.41 (2.51 to 4.65)		
7vPnC serotype 14	10.25 (6.85 to 15.33)	5.22 (2.76 to 9.86)		
7vPnC serotype 18C	3.09 (2.22 to 4.29)	3.45 (2.16 to 5.52)		
7vPnC serotype 19F	7.66 (5.66 to 10.36)	4.85 (3.09 to 7.62)		
7vPnC serotype 23F	10.56 (7.69 to 14.51)	6.51 (4.24 to 10.01)		
Additional serotype 1	3.98 (2.82 to 5.62)	2.83 (1.86 to 4.32)		

Additional serotype 3	2.02 (1.48 to 2.76)	1.4 (0.95 to 2.06)		
Additional serotype 5	5.4 (4.08 to 7.15)	5.12 (3.6 to 7.28)		
Additional serotype 6A	13.6 (9.01 to 20.53)	7.25 (4.75 to 11.06)		
Additional serotype 7F	4.7 (3.26 to 6.78)	3.17 (2.24 to 4.48)		
Additional serotype 19A	13.4 (10.3 to 17.42)	12.03 (8.83 to 16.39)		

Notes:

[213] - Subjects with a determinate OPA antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[214]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	2.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.26
upper limit	3.79

Notes:

[214] - Descriptive

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[215]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	3.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.84
upper limit	5.32

Notes:

[215] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[216]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	2.51

Notes:

[216] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[217]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	4.07

Notes:

[217] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[218]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	2.66

Notes:

[218] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[219]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.56

Notes:

[219] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[220]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	2.73

Notes:

[220] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[221]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	2.39

Notes:

[221] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[222]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	2.34

Notes:

[222] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[223]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.64

Notes:

[223] - Descriptive

Statistical analysis title	7vPnC serotype 6A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[224]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	3.35

Notes:

[224] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[225]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	2.44

Notes:

[225] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[226]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.66

Notes:

[226] - Descriptive

Secondary: Comparison of Pneumococcal Opsonophagocytic Activity (OPA)

Geometric Mean Titers (GMTs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 5)

End point title	Comparison of Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 5)

End point description:

Antibody geometric mean titers as measured by opsonophagocytic activity (OPA) assay for 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMTs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMTs were calculated using all subjects with available data for the specified blood draw.

End point type	Secondary

End point timeframe:

Day 28 (Visit 5)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35[227]		
Units: Titer				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	4626 (3322.5 to 6441.2)	6065 (4590.9 to 8012.5)		
7vPnC serotype 6B	11451 (8290.4 to 15817.9)	10380 (7515.2 to 14336.9)		
7vPnC serotype 9V	6346 (5152.2 to 7817.5)	7555 (5916.7 to 9646.8)		
7vPnC serotype 14	5898 (4481 to 7762.1)	7031 (5195.6 to 9515.5)		
7vPnC serotype 18C	5090 (3428.4 to 7557.7)	6005 (4389.3 to 8214.6)		
7vPnC serotype 19F	1623 (995.2 to 2647.9)	2696 (1831 to 3968.5)		
7vPnC serotype 23F	2752 (2074.6 to 3651.3)	4841 (3574.5 to 6555.1)		
Additional serotype 1	449 (312.8 to 643.2)	347 (228.3 to 527.4)		
Additional serotype 3	113 (89.2 to 143.5)	99 (77 to 126.3)		
Additional serotype 5	296 (158.8 to 549.9)	336 (175.4 to 642.2)		
Additional serotype 6A	9458 (6674.2 to 13404)	10842 (7904.9 to 14870.9)		
Additional serotype 7F	6740 (4933.2 to 9207.7)	6050 (4515 to 8106.7)		
Additional serotype 19A	2120 (1308 to 3435.3)	2340 (1667 to 3285.4)		

Notes:

[227] - Subjects with a determinate OPA antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 4
Statistical analysis description:	
CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[228]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.17

Notes:

[228] - Descriptive

Statistical analysis title	7vPnC serotype 6B
Statistical analysis description:	
CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[229]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.73

Notes:

[229] - Descriptive

Statistical analysis title	7vPnC serotype 9V
Statistical analysis description:	
CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].	
Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[230]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.15

Notes:

[230] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[231]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.25

Notes:

[231] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[232]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.4

Notes:

[232] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[233]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.12

Notes:

[233] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[234]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.85

Notes:

[234] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[235]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	2.22

Notes:

[235] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[236]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.61

Notes:

[236] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[237]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	2.13

Notes:

[237] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[238]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	1.39

Notes:

[238] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[239]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.7

Notes:

[239] - Descriptive

Statistical analysis title	Additional Serotype 19A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[240]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.63

Notes:

[240] - Descriptive

Secondary: Comparison of Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 4)

End point title	Comparison of Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) for the 13 Serotypes for 7vPnC / 13vPnC Relative to MnCC / 13vPnC After Vaccination (Visit 4)

End point description:

Antibody geometric mean titers as measured by opsonophagocytic activity (OPA) assay for 13 pneumococcal serotypes (7vPnC serotypes 4, 6B, 9V, 14, 18C, 19F, 23F and additional serotypes 1, 3, 5, 6A, 7F, and 19A). The 2-sided, 95% CIs for the GMTs were constructed by back transformation of the CIs for the mean of the logarithmically transformed assay results computed using the Student t distribution. Evaluable Immunogenicity population. GMTs were calculated using all subjects with available data for the specified blood draw.

End point type	Secondary

End point timeframe:

Day 7 (Visit 4)

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	35[241]		
Units: Titer				
geometric mean (confidence interval 95%)				
7vPnC serotype 4	5567 (3202.5 to 9678.7)	8339 (6154.1 to 11299.5)		
7vPnC serotype 6B	8082 (5743.5 to 11372.6)	6450 (4477.8 to 9290.2)		
7vPnC serotype 9V	6865 (4826.7 to 9763.7)	7806 (5491.4 to 11095.6)		
7vPnC serotype 14	3596 (2613 to 4948.5)	5994 (4246.9 to 8460.1)		
7vPnC serotype 18C	5833 (3770.5 to 9023.7)	5266 (3779.3 to 7338.4)		
7vPnC serotype 19F	1243 (620.6 to 2489.8)	1855 (1055.8 to 3258.2)		
7vPnC serotype 23F	1575 (987.7 to 2511.7)	1141 (655.1 to 1986.8)		
Additional serotype 1	379 (241.8 to 594.9)	393 (257.2 to 600.3)		
Additional serotype 3	117 (81.3 to 167.5)	104 (75.4 to 143.4)		
Additional serotype 5	200 (111.2 to 358.6)	258 (132.3 to 503.4)		
Additional serotype 6A	8534 (5631.9 to 12931.6)	6199 (4357.6 to 8818.6)		
Additional serotype 7F	4750 (3291.8 to 6852.9)	3760 (2106.7 to 6709.5)		
Additional serotype 19A	1504 (911.2 to 2484.1)	1761 (1242.8 to 2496)		

Notes:

[241] - Subjects with a determinate OPA antibody concentration for the serotypes.

Statistical analyses

Statistical analysis title	7vPnC serotype 6B

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[242]
Parameter estimate	Ratio of geometric mean concentrations
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	2.05

Notes:

[242] - Descriptive

Statistical analysis title	7vPnC serotype 4

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[243]
Parameter estimate	ratio of geometric mean concentrations
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	1.27

Notes:

[243] - Descriptive

Statistical analysis title	7vPnC serotype 9V

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[244]
Parameter estimate	Ratio of geometric mean concentrations
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.44

Notes:

[244] - Descriptive

Statistical analysis title	7vPnC serotype 14

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[245]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.95

Notes:

[245] - Descriptive

Statistical analysis title	7vPnC serotype 18C

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[246]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.91

Notes:

[246] - Descriptive

Statistical analysis title	7vPnC serotype 19F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[247]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	1.62

Notes:

[247] - Descriptive

Statistical analysis title	7vPnC serotype 23F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[248]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	2.81

Notes:

[248] - Descriptive

Statistical analysis title	Additional serotype 1

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[249]
Parameter estimate	ratio of geometric mean titers
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.77

Notes:

[249] - Descriptive

Statistical analysis title	Additional serotype 3

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[250]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.81

Notes:

[250] - Descriptive

Statistical analysis title	Additional serotype 5

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[251]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.85

Notes:

[251] - Descriptive

Statistical analysis title	Additional serotype 6A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[252]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	2.36

Notes:

[252] - Descriptive

Statistical analysis title	Additional serotype 7F

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[253]
Parameter estimate	ratio of geometric mean titers
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	2.44

Notes:

[253] - Descriptive

Statistical analysis title	Additional serotype 19A

Statistical analysis description:

CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures [(7vPnC/13vPnC) – (MnCC/13vPnC)].

Comparison groups	7vPnC / 13vPnC v MnCC / 13vPnC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other[254]
Parameter estimate	ratio of geometric mean titers
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.57

Notes:

[254] - Descriptive

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions Within 4 Days After Vaccination

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions Within 4 Days After Vaccination

End point description:

Local reactions reported using the diary card during the 4-day reactogenicity period after vaccination. Tenderness at injection site scaled as Any (tenderness present) or Significant (present and interfered with limb movement). Redness and swelling at injection site scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); or Severe (greater than [>] 7.0 cm). Subjects may be represented in >1 category. Safety population included all subjects who received the vaccine.

End point type	Other pre-specified

End point timeframe:

Baseline up to 4 days after vaccination on Day 1

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	36[255]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any	92.1	86.1		
Tenderness: Significant	10.5	19.4		
Swelling: Any	10.5	5.6		
Swelling: Mild	2.6	2.8		
Swelling: Moderate	10.5	2.8		
Redness: Any	5.3	5.6		
Redness: Mild	0	2.8		
Redness: Moderate	5.3	2.8		

Notes:

[255] - Subjects with analyzable data for reactogenicity (reported Yes for at least 1 day or No for all days

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events Within 4 Days After Vaccination

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events Within 4 Days After Vaccination

End point description:

Systemic events reported using the diary card during the 4-day reactogenicity period after vaccination. Temperature scaled as Fever ≥38 but less than or equal to (≤) 39 degrees Celsius (C) (mild), >39 but ≤40 degrees C (moderate), or >40 degrees C (severe). Presence of Decreased appetite, Irritability, Increased sleep, Decreased sleep, Rash, and Hives; also scaled as Mild (easily tolerated, minimal discomfort; not interfering with activities), Moderate (sufficiently discomforting to interfere with normal activities), or Severe (may prevent normal activities and require medical intervention). Safety population.

End point type	Other pre-specified

End point timeframe:

Baseline up to 4 days after vaccination on Day 1

End point values	7vPnC / 13vPnC	MnCC / 13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	36[256]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C	2.9	0		
Decreased appetite	7.9	16.7		
Decreased appetite: Mild	7.9	11.1		
Decreased appetite: Moderate	2.6	8.3		
Irritability	18.4	13.9		
Irritability: Mild	13.2	11.1		
Irritability: Moderate	5.3	5.6		
Increased sleep	26.3	33.3		
Increased sleep: Mild	15.8	25		
Increased sleep: Moderate	13.2	13.9		
Increased sleep: Severe	2.6	0		
Decreased sleep	7.9	11.1		
Decreased sleep: Mild	5.3	8.3		
Decreased sleep: Moderate	2.6	2.8		
Rash	5.3	0		
Rash: Mild	5.3	0		

Notes:

[256] - Subjects with analyzable data for reactogenicity(reported Yes for at least 1 day or No for all days)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Day 4 after vaccination for local reactions (LR) and systemic events (SE) or up to Day 194 (Visit 6 / Days 166 to 194 Follow-up Telephone Visit to assess adverse events [AEs])

Adverse event reporting additional description:

The same event may appear as both an AE and a serious adverse event (SAE). However, what is presented are distinct events. An event may be categorized as serious in 1 subject and as nonserious in another subject, or 1 subject may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	7vPnC / 13vPnC

Reporting group description:

13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received 7vPnC in study D118-P8. Adverse Events include Local reactions (LR) and Systemic events (SE) collected on the diary card and reported in the diary-related case report form (systematic assessment) and other Adverse Events collected on the case report form (non-systematic methods). Other Adverse Events N=22; Local reactions N=38; Systemic events N=38.

Reporting group title	MnCC / 13vPnC

Reporting group description:

13vPnC administered as a single 0.5 mL dose IM. Subjects had previously received MnCC in study D118-P8. Adverse Events include Local reactions and Systemic events collected on the diary card and reported in the diary-related case report form (systematic assessment) and other Adverse Events collected on the case report form (non-systematic methods). Other Adverse Events N=20; Local reactions N=36; Systemic events N=36.

Serious adverse events	7vPnC / 13vPnC	MnCC / 13vPnC	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 38 (0.00%)	0 / 36 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	7vPnC / 13vPnC	MnCC / 13vPnC	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 38 (100.00%)	36 / 36 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Skin papilloma			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	4 / 38 (10.53%)	4 / 36 (11.11%)	
occurrences (all)	5	4	
Pyrexia			
subjects affected / exposed	3 / 38 (7.89%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Injection site swelling			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Fever >=38 degrees C but <=39 degrees	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Decreased appetite (LR)	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 38 (7.89%)	6 / 36 (16.67%)	
occurrences (all)	3	6	
Decreased appetite: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 38 (7.89%)	4 / 36 (11.11%)	
occurrences (all)	3	4	
Decreased appetite: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type:			

Systematic			
subjects affected / exposed	1 / 38 (2.63%)	3 / 36 (8.33%)	
occurrences (all)	1	3	
Irritability	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 38 (18.42%)	5 / 36 (13.89%)	
occurrences (all)	7	5	
Irritability: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 38 (13.16%)	4 / 36 (11.11%)	
occurrences (all)	5	4	
Irritability: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 38 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	2	2	
Increased sleep	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 38 (26.32%)	12 / 36 (33.33%)	
occurrences (all)	10	12	
Increased sleep: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 38 (15.79%)	9 / 36 (25.00%)	
occurrences (all)	6	9	
Increased sleep: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one		

	occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed occurrences (all)	5 / 38 (13.16%) 5	5 / 36 (13.89%) 5	
Increased sleep: Severe	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 36 (0.00%) 0	
Decreased sleep	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	4 / 36 (11.11%) 4	
Decreased sleep: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	3 / 36 (8.33%) 3	
Decreased sleep: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 36 (2.78%) 1	
Rash	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed	2 / 38 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Rash: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 38 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Gynaecomastia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	4 / 38 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	4	1	
Oropharyngeal pain			
subjects affected / exposed	3 / 38 (7.89%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Rhinitis allergic			
subjects affected / exposed	1 / 38 (2.63%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Cough			
subjects affected / exposed	1 / 38 (2.63%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Nasal congestion			
subjects affected / exposed	1 / 38 (2.63%)	1 / 36 (2.78%)	
occurrences (all)	1	1	

Respiratory disorder			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 38 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Joint sprain			
subjects affected / exposed	2 / 38 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Ankle fracture			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Avulsion fracture			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Clavicle fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Concussion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Excoriation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Hand fracture			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Muscle strain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Traumatic brain injury			

subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Congenital, familial and genetic disorders			
Congenital flat feet			
subjects affected / exposed	0 / 38 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 38 (5.26%)	3 / 36 (8.33%)	
occurrences (all)	2	3	
Hypersomnia			
subjects affected / exposed	1 / 38 (2.63%)	2 / 36 (5.56%)	
occurrences (all)	3	2	
Somnolence			
subjects affected / exposed	0 / 38 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Dizziness			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Presyncope			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Lymphoid tissue hyperplasia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Cerumen impaction			

subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Ear congestion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Ear pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 38 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Dermatitis contact			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Ingrowing nail			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Tenderness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	35 / 38 (92.11%)	31 / 36 (86.11%)	
occurrences (all)	35	31	
Tenderness: Significant	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed	4 / 38 (10.53%)	7 / 36 (19.44%)	
occurrences (all)	4	7	
Swelling: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 38 (10.53%)	2 / 36 (5.56%)	
occurrences (all)	4	2	
Swelling: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 38 (2.63%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Swelling: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 38 (10.53%)	1 / 36 (2.78%)	
occurrences (all)	4	1	
Redness: Any	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 38 (5.26%)	2 / 36 (5.56%)	
occurrences (all)	2	2	
Redness: Mild	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Redness: Moderate	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed	2 / 38 (5.26%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Renal and urinary disorders Haematuria subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Patellofemoral pain syndrome subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Infections and infestations Otitis externa subjects affected / exposed	1 / 38 (2.63%)	2 / 36 (5.56%)	
occurrences (all)	1	2	
Pharyngitis subjects affected / exposed	2 / 38 (5.26%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Acute sinusitis subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Bronchitis subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Gastritis viral subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pneumonia subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Sinusitis			

subjects affected / exposed	0 / 38 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 38 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Dehydration			
subjects affected / exposed	1 / 38 (2.63%)	0 / 36 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 August 2009	Changed the study phase from 3 to 2, modified assessments at study visits, changed the duration of the study and of subject participation, the collection period for AEs was modified, clarified the administration of prohibited vaccines during the study and added categorizing criteria for systemic events.
30 October 2009	Removed the measurement of the activity of B-cells, and modified safety assessments at baseline, visit 4 and visit 6.
24 February 2010	Modified the definition of evaluable subjects and modified the assessments at baseline.
29 March 2010	Added the physical examinations to the study procedures.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported