

**Clinical trial results:****A Phase 3, Open-label Study to Evaluate Persistence of the Antibody Response Elicited by Pneumococcal Conjugate Vaccine in Healthy Children Who Have Been Previously Immunized With a 4-Dose Series of a Pneumococcal Conjugate Vaccine During Infancy in Study 6096A1-008-EU and the Safety and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine Administered at Least 24 Months After the Last Toddler Dose of Pneumococcal Conjugate Vaccine****Summary**

EudraCT number	2009-015321-37
Trial protocol	FR
Global end of trial date	17 November 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	6096A1-3021FR
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01026038
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851016

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	25 May 2011
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 November 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the antibody levels to the 13 pneumococcal vaccine serotypes not earlier than 24 months and the immune response to 13-valent pneumococcal conjugate vaccine(13vPnC) serotypes 1 month after a dose of 13vPnC administered not earlier than 24 months after the toddler dose in study 6096A1-008-EU, as measured by serotype specific immunoglobulin G (IgG) concentrations.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 April 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 262
Worldwide total number of subjects	262
EEA total number of subjects	262

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)	262
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 263 subjects who had received a 4-dose vaccination series of pneumococcal conjugate vaccine as part of study 6096A1-008 (NCT00366678) were enrolled for this study. Out of those 1 subject was a screen failure and was not included in results.

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	13vPnC/13vPnC/13vPnC

Arm description:

Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose (0.5 milliliter [mL]) of 13vPnC vaccine intramuscularly (IM), 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

Arm title	7vPnC/7vPnC/13vPnC
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Arm description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose (0.5 mL) of 13vPnC vaccine IM, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7vPnC/7vPnC vaccine.

Arm title	7vPnC/13vPnC/13vPnC
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Arm description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.

Arm type	Experimental
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Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose (0.5 mL) of 13vPnC vaccine IM, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7vPnC/13vPnC vaccine.

Number of subjects in period 1	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC
Started	130	65	67
Completed	129	64	67
Not completed	1	1	0
Lost to follow-up	1	1	-

Baseline characteristics

Reporting groups

Reporting group title	13vPnC/13vPnC/13vPnC
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Reporting group description:

Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

Reporting group title	7vPnC/7vPnC/13vPnC
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Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.

Reporting group title	7vPnC/13vPnC/13vPnC
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Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.

Reporting group values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC
Number of subjects	130	65	67
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	3.4 ± 0.25	3.4 ± 0.24	3.5 ± 0.25
Gender categorical Units: Subjects			
Female	70	29	40
Male	60	36	27

Reporting group values	Total		
Number of subjects	262		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	-		
Gender categorical Units: Subjects			
Female	139		
Male	123		

End points

End points reporting groups

Reporting group title	13vPnC/13vPnC/13vPnC
Reporting group description:	
Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.	
Reporting group title	7vPnC/7vPnC/13vPnC
Reporting group description:	
Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.	
Reporting group title	7vPnC/13vPnC/13vPnC
Reporting group description:	
Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.	

Primary: Serotype-specific Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentration (GMC) 1 Month After Single Dose of 13 Valent Pneumococcal Conjugate (13vPnC) Vaccine

End point title	Serotype-specific Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentration (GMC) 1 Month After Single Dose of 13 Valent Pneumococcal Conjugate (13vPnC) Vaccine
End point description:	
Antibody GMC as measured by microgram per millilitre (mcg/mL) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% confidence interval (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Evaluable immunogenicity population: eligible subjects, randomised, blood drawn within required timeframes, at least 1 valid and determinate assay result for proposed analysis, received no prohibited vaccines, no major protocol violations.	
End point type	Primary
End point timeframe:	
One month after vaccination	

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	120 ^[1]	57 ^[2]	58 ^[3]	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	10.34 (8.94 to 11.97)	12.79 (10 to 16.35)	8.98 (6.98 to 11.56)	
Serotype 6B	31.62 (27.02 to 37.01)	51.07 (38.65 to 67.49)	35.38 (27.25 to 45.93)	
Serotype 9V	6.76 (5.9 to 7.73)	6.5 (5.31 to 7.95)	6.19 (5.04 to 7.61)	
Serotype 14	21.55 (18.41 to 25.24)	21.15 (16.89 to 26.48)	20.73 (16.45 to 26.12)	

Serotype 18C	4.56 (3.93 to 5.29)	6.12 (4.89 to 7.65)	5.35 (4.27 to 6.71)	
Serotype 19F	16.59 (13.57 to 20.28)	12.07 (9.35 to 15.59)	15.09 (11.17 to 20.39)	
Serotype 23F	8.68 (7.5 to 10.03)	10.87 (8.3 to 14.22)	9.1 (7.34 to 11.28)	
Serotype 1	10.72 (9.17 to 12.52)	2.96 (2.45 to 3.59)	20.69 (16.14 to 26.53)	
Serotype 3	1.81 (1.46 to 2.23)	1.6 (1.19 to 2.17)	2.07 (1.66 to 2.59)	
Serotype 5	10 (8.63 to 11.58)	2.86 (2.37 to 3.46)	19.2 (14.93 to 24.7)	
Serotype 6A	23.09 (19.5 to 27.33)	14.38 (10.53 to 19.64)	18.6 (13.87 to 24.93)	
Serotype 7F	8.23 (7.11 to 9.52)	5.04 (4.16 to 6.11)	8.02 (6.66 to 9.67)	
Serotype 19A	17.1 (14.54 to 20.11)	8.58 (6.7 to 10.99)	16.46 (13.42 to 20.19)	

Notes:

[1] - N= number of subjects with determinate IgG antibody concentration to serotype.

[2] - N= number of subjects with determinate IgG antibody concentration to serotype.

[3] - N= number of subjects with determinate IgG antibody concentration to serotype

Statistical analyses

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.07

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.52

Statistical analysis title	4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	1.96

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	0.84

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.2

Statistical analysis title	6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	2.04

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.04

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.32

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.39

Statistical analysis title	9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.39

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.34

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.37

Statistical analysis title	14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.4

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.97

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.11

Statistical analysis title	18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMCratio
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.56

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.94

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.55

Statistical analysis title	19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.19

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.05

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.95

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.25

Statistical analysis title	23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.64

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	3.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.76
upper limit	4.74

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.68

Statistical analysis title	1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.2

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.59

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.23

Statistical analysis title	3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.15

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	3.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.68
upper limit	4.54

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.68

Statistical analysis title	5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	0.2

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	2.23

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.72

Statistical analysis title	6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.13

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	2.08

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.3

Statistical analysis title	7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.83

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	2.63

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.37

Statistical analysis title	19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.72

Primary: Percentage of Subjects with Prespecified Local Reactions

End point title	Percentage of Subjects with Prespecified Local Reactions
End point description:	
Local reactions (redness, swelling and pain) were reported using electronic diary. Redness and swelling were recorded in caliper units (range 1 to 14+), each caliper unit represented 0.5 centimeter (cm). Categorized as any, absent (no redness or swelling present; 0 caliper units), mild (0.5 to 2.0 cm; 1 to 4 caliper units); moderate (2.5 to 7.0 cm; 5 to 14 caliper units); or severe (greater than (>)7.0 cm; >14 caliper units). Pain was categorized as any, mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity. Subjects may be reported in more than 1 category. Safety population: all subjects who received the single dose of 13vPnC vaccination. n = number of subjects reporting yes for at least 1 day or no for all days, for each group, respectively.	
End point type	Primary
End point timeframe:	
Seven days after vaccination	

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	130	64	64	
Units: percentage of subjects				
number (not applicable)				
Pain: Any (n= 112, 52, 53)	55.4	55.8	64.2	
Pain: Mild (n= 109, 51, 51)	50.5	49	56.9	
Pain: Moderate (n= 95, 47, 48)	17.9	25.5	20.8	
Pain: Severe (n= 90, 43, 45)	1.1	2.3	2.2	
Swelling: Any (101, 48, 47)	39.6	41.7	27.7	
Swelling: Mild (n= 96, 48, 47)	28.1	35.4	23.4	
Swelling: Moderate (n= 97, 44, 46)	24.7	20.5	10.9	

Swelling: Severe (n= 90, 43, 45)	0	2.3	0	
Redness: Any (n= 105, 50, 50)	48.6	54	46	
Redness: Mild (n= 101, 49, 48)	38.6	40.8	37.5	
Redness: Moderate (n= 95, 45, 47)	22.1	31.1	17	
Redness: Severe (n= 90, 43, 45)	0	2.3	0	

Statistical analyses

Statistical analysis title	Pain (Any)
Statistical analysis description:	
Pain (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Pain (Any)
Statistical analysis description:	
Pain (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.429
Method	Fisher exact

Statistical analysis title	Pain (Any)
Statistical analysis description:	
Pain (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.314
Method	Fisher exact

Statistical analysis title	Pain (Mild)
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Statistical analysis description:

Pain (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Pain (Mild)
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Statistical analysis description:

Pain (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.552
Method	Fisher exact

Statistical analysis title	Pain (Mild)
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Statistical analysis description:

Pain (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.499
Method	Fisher exact

Statistical analysis title	Pain (Moderate)
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Statistical analysis description:

Pain (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.376
Method	Fisher exact

Statistical analysis title	Pain (Moderate)
Statistical analysis description:	
Pain (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.633
Method	Fisher exact

Statistical analysis title	Pain (Moderate)
Statistical analysis description:	
Pain (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.658
Method	Fisher exact

Statistical analysis title	Pain (Severe)
Statistical analysis description:	
Pain (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.544
Method	Fisher exact

Statistical analysis title	Pain (Severe)
Statistical analysis description:	
Pain (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Pain (Severe)
Statistical analysis description: Pain (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Swelling (Any)
Statistical analysis description: Swelling (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.859
Method	Fisher exact

Statistical analysis title	Swelling (Any)
Statistical analysis description: Swelling (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.197
Method	Fisher exact

Statistical analysis title	Swelling (Any)
Statistical analysis description: Swelling (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.198
Method	Fisher exact

Statistical analysis title	Swelling (Mild)
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Statistical analysis description:

Swelling (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.443
Method	Fisher exact

Statistical analysis title	Swelling (Mild)
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Statistical analysis description:

Swelling (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.261
Method	Fisher exact

Statistical analysis title	Swelling (Mild)
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Statistical analysis description:

Swelling (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.687
Method	Fisher exact

Statistical analysis title	Swelling (Moderate)
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Statistical analysis description:

Swelling (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between

13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.671
Method	Fisher exact

Statistical analysis title	Swelling (Moderate)
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Statistical analysis description:

Swelling (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.253
Method	Fisher exact

Statistical analysis title	Swelling (Moderate)
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Statistical analysis description:

Swelling (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.074
Method	Fisher exact

Statistical analysis title	Swelling (Severe)
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Statistical analysis description:

Swelling (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.323
Method	Fisher exact

Statistical analysis title	Swelling (Severe)
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Statistical analysis description:

Swelling (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.489
Method	Fisher exact

Statistical analysis title

Redness (Any)

Statistical analysis description:

Redness (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.607
Method	Fisher exact

Statistical analysis title

Redness (Any)

Statistical analysis description:

Redness (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.549
Method	Fisher exact

Statistical analysis title

Redness (Any)

Statistical analysis description:

Redness (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.864
Method	Fisher exact

Statistical analysis title	Redness (Mild)
Statistical analysis description:	
Redness (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.859
Method	Fisher exact

Statistical analysis title	Redness (Mild)
Statistical analysis description:	
Redness (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.836
Method	Fisher exact

Statistical analysis title	Redness (Mild)
Statistical analysis description:	
Redness (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Redness (Moderate)
Statistical analysis description:	
Redness (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.297
Method	Fisher exact

Statistical analysis title	Redness (Moderate)
Statistical analysis description: Redness (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.145
Method	Fisher exact

Statistical analysis title	Redness (Moderate)
Statistical analysis description: Redness (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.517
Method	Fisher exact

Statistical analysis title	Redness (Severe)
Statistical analysis description: Redness (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.323
Method	Fisher exact

Statistical analysis title	Redness (Severe)
Statistical analysis description: Redness (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.489
Method	Fisher exact

Primary: Percentage of Subjects With Prespecified Systemic Events

End point title	Percentage of Subjects With Prespecified Systemic Events
End point description:	
Systemic events (any fever greater than or equals to [\geq]38 degree celsius [C], vomiting, diarrhea, and fatigue) were reported using electronic diary. Fever categorized as ≥ 38 to less than or equals to (\leq)39 degree C; >39 to ≤ 40 degree C; >40 degree C. Vomiting: mild (1-2 times/day); moderate (>2 times/day); severe (requires intravenous hydration). Diarrhea: mild (2-3 loose stools/day); moderate (4-5 stools/day); severe (≥ 6 loose stools/day). Fatigue: mild (does not interfere with activity); moderate (some interference with activity); severe (prevents daily routine activity). Subjects may be reported in more than 1 category. Safety population: all subjects who received the single dose of 13vPnC vaccination. n = number of subjects reporting yes for at least 1 day or no for all days, for each group, respectively.	
End point type	Primary
End point timeframe:	
Seven days after vaccination	

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	130	64	64	
Units: percentage of subjects				
number (not applicable)				
Fever ≥ 38 to ≤ 39 degree C (n= 93, 49, 46)	15.1	28.6	19.6	
Fever >39 to ≤ 40 degree C (n= 92, 43, 46)	2.2	4.7	2.2	
Fever >40 degree C (n= 90, 43, 45)	0	0	2.2	
Vomiting: Any (n= 91, 44, 45)	3.3	9.1	6.7	
Vomiting: Mild (n= 91, 44, 45)	3.3	9.1	6.7	
Vomiting: Moderate (n= 90, 43, 45)	0	0	0	
Vomiting: Severe (n= 90, 43, 45)	0	0	0	
Diarrhea: Any (n= 90, 45, 47)	8.9	17.8	8.5	
Diarrhea: Mild (n= 90, 45, 47)	8.9	17.8	8.5	
Diarrhea: Moderate (n= 90, 43, 45)	1.1	0	0	
Diarrhea: Severe (n= 90, 43, 45)	0	0	0	
Fatigue: Any (n= 103, 54, 48)	40.8	51.9	31.3	
Fatigue: Mild (n= 100, 49, 48)	34	34.7	20.8	
Fatigue: Moderate (n= 96, 49, 46)	16.7	30.6	15.2	
Fatigue: Severe (n= 92, 43, 45)	3.3	2.3	2.2	

Statistical analyses

Statistical analysis title	Fever (≥ 38 degree C to ≤ 39 degree C)
Statistical analysis description: Fever (≥ 38 degree C to ≤ 39 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.075
Method	Fisher exact

Statistical analysis title	Fever (≥ 38 degree C to ≤ 39 degree C)
Statistical analysis description: Fever (≥ 38 degree C to ≤ 39 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC	
Comparison groups	7vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.345
Method	Fisher exact

Statistical analysis title	Fever (≥ 38 degree C to ≤ 39 degree C)
Statistical analysis description: Fever (≥ 38 degree C to ≤ 39 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.628
Method	Fisher exact

Statistical analysis title	Fever (≥ 39 degree C to ≤ 40 degree C)
Statistical analysis description: Fever (≥ 39 degree C to ≤ 40 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.592
Method	Fisher exact

Statistical analysis title	Fever (≥ 39 degree C to ≤ 40 degree C)
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Statistical analysis description:

Fever (≥ 39 degree C to ≤ 40 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.608
Method	Fisher exact

Statistical analysis title	Fever (≥ 39 degree C to ≤ 40 degree C)
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Statistical analysis description:

Fever (≥ 39 degree C to ≤ 40 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fever (> 40 degree C)
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Statistical analysis description:

Fever (> 40 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fever (> 40 degree C)
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Statistical analysis description:

Fever (> 40 degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between

13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.333
Method	Fisher exact

Statistical analysis title	Vomiting (Any)
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Statistical analysis description:

Vomiting (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.215
Method	Fisher exact

Statistical analysis title	Vomiting (Any)
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Statistical analysis description:

Vomiting (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.714
Method	Fisher exact

Statistical analysis title	Vomiting (Any)
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Statistical analysis description:

Vomiting (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.397
Method	Fisher exact

Statistical analysis title	Vomiting (Mild)
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Statistical analysis description:

Vomiting (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.215
Method	Fisher exact

Statistical analysis title	Vomiting (Mild)
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Statistical analysis description:

Vomiting (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.714
Method	Fisher exact

Statistical analysis title	Vomiting (Mild)
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Statistical analysis description:

Vomiting (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.397
Method	Fisher exact

Statistical analysis title	Diarrhea (Any)
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Statistical analysis description:

Diarrhea (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.161
Method	Fisher exact

Statistical analysis title	Diarrhea (Any)
Statistical analysis description:	
Diarrhea (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.226
Method	Fisher exact

Statistical analysis title	Diarrhea (Any)
Statistical analysis description:	
Diarrhea (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Diarrhea (Mild)
Statistical analysis description:	
Diarrhea (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.161
Method	Fisher exact

Statistical analysis title	Diarrhea (Mild)
Statistical analysis description:	
Diarrhea (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.226
Method	Fisher exact

Statistical analysis title	Diarrhea (Mild)
Statistical analysis description: Diarrhea (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Diarrhea (Moderate)
Statistical analysis description: Diarrhea (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Diarrhea (Moderate)
Statistical analysis description: Diarrhea (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fatigue (Any)
Statistical analysis description: Fatigue (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.237
Method	Fisher exact

Statistical analysis title	Fatigue (Any)
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Statistical analysis description:

Fatigue (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	Fisher exact

Statistical analysis title	Fatigue (Any)
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Statistical analysis description:

Fatigue (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.285
Method	Fisher exact

Statistical analysis title	Fatigue (Mild)
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Statistical analysis description:

Fatigue (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fatigue (Mild)
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Statistical analysis description:

Fatigue (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between

7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.174
Method	Fisher exact

Statistical analysis title	Fatigue (Mild)
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Statistical analysis description:

Fatigue (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.125
Method	Fisher exact

Statistical analysis title	Fatigue (Moderate)
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Statistical analysis description:

Fatigue (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.058
Method	Fisher exact

Statistical analysis title	Fatigue (Moderate)
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Statistical analysis description:

Fatigue (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.092
Method	Fisher exact

Statistical analysis title	Fatigue (Moderate)
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Statistical analysis description:

Fatigue (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fatigue (Severe)
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Statistical analysis description:

Fatigue (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fatigue (Severe)
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Statistical analysis description:

Fatigue (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fatigue (Severe)
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Statistical analysis description:

Fatigue (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.99
Method	Fisher exact

Secondary: Serotype-specific Pneumococcal IgG GMC Prior to Single Dose of 13vPnC Vaccine

End point title	Serotype-specific Pneumococcal IgG GMC Prior to Single Dose of 13vPnC Vaccine
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End point description:

IgG GMC to the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using a standardized anti-pneumococcal IgG enzymelinked immunosorbent assay (ELISA). CIs for GMC are back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population: eligible subjects, randomized, blood drawn within required timeframes, at least 1 valid and determinate assay result for proposed analysis, received no prohibited vaccines, no major protocol violations.

End point type	Secondary
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End point timeframe:

Up to 7 days before vaccination

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	120 ^[4]	57 ^[5]	58 ^[6]	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	0.17 (0.15 to 0.21)	0.23 (1.43 to 3.11)	0.18 (0.15 to 0.22)	
Serotype 6B	2.86 (2.35 to 3.48)	4.1 (1.19 to 2.05)	3.21 (2.37 to 4.36)	
Serotype 9V	0.72 (0.6 to 0.85)	0.92 (0.09 to 0.2)	0.71 (0.58 to 0.87)	
Serotype 14	0.77 (0.61 to 0.98)	0.74 (0.29 to 0.75)	0.59 (0.42 to 0.83)	
Serotype 18C	0.21 (0.17 to 0.25)	0.36 (0.89 to 1.41)	0.23 (0.18 to 0.28)	
Serotype 19F	2.22 (1.67 to 2.95)	2.11 (1.5 to 2.38)	1.44 (1.04 to 2.02)	
Serotype 23F	1.26 (1 to 1.58)	1.56 (0.15 to 0.3)	1.18 (0.92 to 1.52)	
Serotype 1	0.35 (0.29 to 0.43)	0.14 (2.6 to 4.41)	0.28 (0.23 to 0.34)	
Serotype 3	0.5 (0.35 to 0.71)	0.47 (0.18 to 0.3)	0.42 (0.3 to 0.58)	
Serotype 5	1.28 (1.07 to 1.53)	1.12 (2.96 to 5.68)	1.41 (1.19 to 1.67)	
Serotype 6A	4.05 (3.25 to 5.04)	1.89 (0.72 to 1.17)	2.47 (1.91 to 3.21)	
Serotype 7F	0.65 (0.55 to 0.78)	0.21 (0.52 to 1.06)	0.77 (0.62 to 0.96)	
Serotype 19A	6.16 (4.88 to 7.79)	3.38 (0.28 to 0.47)	4.63 (3.43 to 6.26)	

Notes:

[4] - N= number of subjects with determinate IgG antibody concentration to serotype.

[5] - N= number of subjects with determinate IgG antibody concentration to serotype.

[6] - N= number of subjects with determinate IgG antibody concentration to serotype.

Statistical analyses

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.28

Statistical analysis title	4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.79

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.27

Statistical analysis title	6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.94

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.03

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.33

Statistical analysis title	9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.8

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.58

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.97

Statistical analysis title	14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	2.03

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	0.78

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.23

Statistical analysis title	18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	2.25

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.68

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	2.44

Statistical analysis title	19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	2.51

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.15

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.52

Statistical analysis title	23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	2.01

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	2.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	3.73

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.79

Statistical analysis title	1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	0.74

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.87

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	2.09

Statistical analysis title	3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	2.15

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.52

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.2

Statistical analysis title	5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	1.1

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	2.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.52
upper limit	3.02

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	2.3

Statistical analysis title	6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.14

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	3.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.23
upper limit	4.33

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.17

Statistical analysis title	7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	0.4

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	2.66

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.94

Statistical analysis title	19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.13

Secondary: Serotype-specific Pneumococcal IgG GMC at 4 to 7 Days After the Single Dose of 13vPnC Vaccine

End point title	Serotype-specific Pneumococcal IgG GMC at 4 to 7 Days After the Single Dose of 13vPnC Vaccine
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End point description:

IgG GMC to the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using a standardized anti-pneumococcal IgG ELISA. CIs for GMC are back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population: eligible subjects, randomized, blood drawn within required timeframes, at least 1 valid and determinate assay result for proposed analysis, received no prohibited vaccines, no major protocol violations.

End point type	Secondary
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End point timeframe:

Four to seven days after vaccination

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44 ^[7]	18 ^[8]	22 ^[9]	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	2.96 (1.67 to 5.24)	4.66 (2.01 to 10.82)	3.85 (3.5 to 11.26)	
Serotype 6B	17.78 (12.5 to 25.3)	19.15 (8.84 to 41.48)	16.26 (3.51 to 18.23)	
Serotype 9V	3.49 (2.39 to 5.09)	3.15 (1.75 to 5.66)	3.2 (0.94 to 1.72)	
Serotype 14	5.55 (3.32 to 9.3)	5.67 (2.29 to 13.99)	4.52 (5.29 to 18.19)	
Serotype 18C	2.31 (1.36 to 3.91)	3.34 (1.66 to 6.72)	2.51 (3.95 to 13.78)	
Serotype 19F	11.7 (7.21 to 19)	6.88 (2.98 to 15.86)	8.51 (1.72 to 5.51)	
Serotype 23F	5.24 (3.49 to 7.87)	5.82 (2.97 to 11.4)	6.28 (7.12 to 15.5)	
Serotype 1	4.24 (2.48 to 7.26)	0.56 (0.27 to 1.18)	8 (1.7 to 8.74)	
Serotype 3	1.24 (0.79 to 1.95)	1.12 (0.56 to 2.25)	1.24 (8.1 to 32.66)	
Serotype 5	6 (4.16 to 8.66)	1.43 (0.99 to 2.06)	9.81 (1.86 to 5.5)	
Serotype 6A	13.86 (9.69 to 19.83)	4.46 (2.18 to 9.12)	7.37 (2.14 to 9.52)	
Serotype 7F	3.55 (2.35 to 5.36)	1.23 (0.69 to 2.21)	3.08 (1.33 to 4.73)	
Serotype 19A	13.07 (9.63 to 17.74)	5.09 (3.17 to 8.19)	10.5 (4.38 to 16.55)	

Notes:

[7] - N= number of subjects with determinate IgG antibody concentration to serotype.

[8] - N= number of subjects with determinate IgG antibody concentration to serotype.

[9] - N= number of subjects with determinate IgG antibody concentration to serotype.

Statistical analyses

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	1.76

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.99

Statistical analysis title	4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	3.86

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.99

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	2.22

Statistical analysis title	6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2.79

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	2.19

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	2.06

Statistical analysis title	9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.13

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	2.55

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	3

Statistical analysis title	14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	3.72

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	1.68

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	2.1

Statistical analysis title	18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	3.64

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	4.12

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	3.14

Statistical analysis title	19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	2.21

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.89

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.67

Statistical analysis title	23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	2.16

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	7.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.86
upper limit	19.78

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	1.31

Statistical analysis title	1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.21

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	2.3

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.97

Statistical analysis title	3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	2.07

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.18
upper limit	8.09

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.61

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.13

Statistical analysis title	5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	0.31

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	3.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	6.4

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	3.69

Statistical analysis title	6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.37

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	2.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	5.98

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	2.28

Statistical analysis title	7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	0.92

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	2.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	4.39

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	2.05

Statistical analysis title	19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMC ratio
Point estimate	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	0.89

Secondary: Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) Prior to Single Dose of 13vPnC Vaccine

End point title	Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) Prior to Single Dose of 13vPnC Vaccine
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End point description:

Pneumococcal OPA GMTs for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using a microcolony OPA (mcOPA) assay. CIs for GMT are back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. n= number of subjects with a determinate OPA antibody titer to the given serotype. -99999 to 99999 for 13vPnC/13vPnC/13vPnC= Since all values for serotype 5 in 13v/13v/13v treatment arm was less than lower limit of quantification (LLOQ), values was set to 0.5 multiplied by (*)limit of detection (LOD [8]) = 4. Hence variability (standard error) could not be estimated; CI was not estimable. -99999 to 99999 for 7vPnC/7vPnC/13vPnC= Since all values for serotype 5 in 7v/7v/13v treatment arm was less than LLOQ, values was set to 0.5*LOD (8) = 4. Hence variability (standard error) could not be estimated; CI was not estimable.

End point type	Secondary
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End point timeframe:

Up to 7 days before vaccination

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44 ^[10]	18 ^[11]	22 ^[12]	
Units: Geometric mean titers				
geometric mean (confidence interval 95%)				
Serotype 4 (n= 40, 14, 19)	8 (4.4 to 13.1)	46 (7.8 to 268.5)	45 (10.6 to 190.6)	
Serotype 6B (n= 38, 16, 21)	245 (92.6 to 646.9)	247 (49.1 to 1241.8)	332 (84.4 to 1304.3)	
Serotype 9V (n= 40, 18, 21)	43 (16.3 to 111.9)	36 (8.6 to 149.1)	52 (14.6 to 187.8)	
Serotype 14 (n= 39, 16, 20)	98 (39.7 to 242.9)	40 (9.2 to 174.2)	49 (14.4 to 163.9)	
Serotype 18C (n= 42, 17, 19)	14 (6.9 to 27.7)	76 (15.7 to 363)	28 (7.2 to 109.7)	
Serotype 19F (n= 43, 17, 21)	48 (20.8 to 112.5)	49 (13 to 182.6)	40 (14 to 112.5)	
Serotype 23F (n= 43, 16, 21)	52 (22.5 to 120.3)	61 (13.1 to 284.3)	178 (54.6 to 578.7)	
Serotype 1 (n= 44, 18, 22)	6 (4.5 to 7.5)	5 (3.4 to 6.5)	10 (6.9 to 15)	
Serotype 3 (n= 42, 17, 21)	20 (11.8 to 34.6)	10 (4.4 to 22.2)	18 (12.1 to 28)	
Serotype 5 (n= 44, 18, 22)	4 (-99999 to 99999)	4 (-99999 to 99999)	4 (3.6 to 5.6)	
Serotype 6A (n= 44, 16, 21)	170 (72.8 to 395.5)	10 (3.4 to 31.4)	75 (22.3 to 253.9)	
Serotype 7F (n= 39, 16, 21)	60 (22.5 to 157.8)	47 (10 to 225.2)	389 (112 to 1351.1)	
Serotype 19A (n= 41, 18, 20)	118 (58.2 to 239.7)	25 (7.4 to 82)	124 (46.4 to 330.2)	

Notes:

[10] - N= number of subjects analysed within a given treatment group.

[11] - N= number of subjects analysed within a given treatment group.

[12] - N= number of subjects analysed within a given treatment group.

Statistical analyses

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT Ratio
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.73

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT Ratio
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.64

Statistical analysis title	4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	5.46

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	5.85

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	3.72

Statistical analysis title	6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	5.37

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	6.25

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	3.92

Statistical analysis title	9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	4.43

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	12.35

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	9.05

Statistical analysis title	14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	5.14

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.8

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.12
upper limit	2.03

Statistical analysis title	18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	14.92

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	4.36

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	4.84

Statistical analysis title	19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	6.65

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	4.17

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	1.24

Statistical analysis title	23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	2.08

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.97

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.88

Statistical analysis title	1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	0.77

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	4.9

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	2.48

Statistical analysis title	3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	1.45

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.15

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.03

Statistical analysis title	5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.06

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	16.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.56
upper limit	76.14

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	9.06

Statistical analysis title	6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.78

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	7.07

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	0.74

Statistical analysis title	7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.84

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.35
upper limit	16.98

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	3.23

Statistical analysis title	19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	0.85

Secondary: Serotype-specific OPA GMTs 1 Month After Single Dose of 13vPnC Vaccine

End point title	Serotype-specific OPA GMTs 1 Month After Single Dose of 13vPnC Vaccine
End point description: Serotype-specific pneumococcal OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using mcOPA assay. CIs for GMT are back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. n= number of subjects with a determinate OPA antibody titer to the given serotype.	
End point type	Secondary
End point timeframe: One month after vaccination	

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	120 ^[13]	57 ^[14]	58 ^[15]	
Units: Geometric mean titers				
geometric mean (confidence interval 95%)				
Serotype 4 (n= 117, 53, 55)	5465 (4698.9 to 6356.4)	5208 (4301.7 to 6304.2)	5487 (4236.9 to 7106.4)	
Serotype 6B (n= 117, 57, 56)	6684 (5638.4 to 7924.4)	10042 (7697.5 to 13101.6)	8983 (7006.9 to 11516.8)	
Serotype 9V (n= 116, 54, 55)	5120 (4456.1 to 5882.6)	4052 (3291 to 4989.7)	5221 (4110.4 to 6630.7)	
Serotype 14 (n= 115, 54, 55)	2780 (2374.7 to 3254.6)	3079 (2450.6 to 3869.4)	2979 (2232.9 to 3973.4)	
Serotype 18C (n= 117, 54, 57)	7711 (6589.6 to 9023.3)	7091 (5655.9 to 8889.9)	8431 (6740.3 to 10545.7)	
Serotype 19F (n= 118, 57, 57)	1319 (1030.5 to 1689.5)	1721 (1316.8 to 2250.3)	1914 (1350.6 to 2712.5)	
Serotype 23F (n= 118, 53, 56)	2427 (2063.6 to 2855)	2411 (1792.5 to 3242.4)	2673 (2091.2 to 3417.3)	
Serotype 1 (n= 119, 56, 57)	613 (525.2 to 715.7)	197 (161.4 to 239.4)	1212 (968 to 1516.9)	
Serotype 3 (n= 118, 56, 58)	244 (214.7 to 276.4)	173 (139.5 to 214.5)	291 (239.4 to 353.7)	
Serotype 5 (n= 118, 55, 54)	455 (358.7 to 537.9)	390 (281.2 to 541.8)	728 (545 to 972.2)	
Serotype 6A (n= 117, 55, 55)	5580 (4593.6 to 6777)	5596 (4276.6 to 7321.2)	5982 (4450.7 to 8041.1)	
Serotype 7F (n= 118, 56, 54)	4323 (3794.4 to 4925.1)	8048 (6500.9 to 9962.2)	4056 (3092.2 to 5321.2)	
Serotype 19A (n= 116, 53, 54)	1212 (1048.1 to 1400.7)	1249 (956.5 to 1632.3)	1568 (1249.7 to 1966.1)	

Notes:

[13] - N= number of subjects analysed within a given treatment group

[14] - N= number of subjects analysed within a given treatment group

[15] - N= number of subjects analysed within a given treatment group

Statistical analyses

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.38

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.3

Statistical analysis title	4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.3

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.9

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	1.01

Statistical analysis title	6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.59

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.63

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.27

Statistical analysis title	9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.05

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.21

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.25

Statistical analysis title	14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.46

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.43

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.2

Statistical analysis title	18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.15

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC

Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.15

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.03

Statistical analysis title	19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.44

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.37

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.23

Statistical analysis title	23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.29

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	4.06

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.66

Statistical analysis title	1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.12
upper limit	0.22

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.78

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.06

Statistical analysis title	3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	0.78

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.62

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	0.87

Statistical analysis title	5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.79

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.4

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.31

Statistical analysis title	6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.39

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	0.7

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.38

Statistical analysis title	7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	2.69

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.28

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	1.02

Statistical analysis title	19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMT ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.1

Secondary: Percentage of Subjects With at Least 1/8 Serotype-specific OPA GMTs After Single Dose of 13vPnC Vaccine

End point title	Percentage of Subjects With at Least 1/8 Serotype-specific OPA GMTs After Single Dose of 13vPnC Vaccine
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End point description:

Percentage of subjects with at least 1/8 serotype-specific pneumococcal OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) determined in the blood samples of all subjects. The data was not collected as planned as the additional, more stringent qualification and validation of the improved mcOPA assays used in this study did not support 1/8 for the quantitation of a serum response and thus the established LLOQ was used for the mcOPA assay.

End point type	Secondary
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End point timeframe:

One month after vaccination

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[16]	0 ^[17]	0 ^[18]	
Units: percentage of subjects				
number (not applicable)				

Notes:

[16] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[17] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[18] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With at Least 1/2048 OPA GMTs for Serotype 7F After Single Dose of 13vPnC Vaccine

End point title	Percentage of Subjects With at Least 1/2048 OPA GMTs for Serotype 7F After Single Dose of 13vPnC Vaccine
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End point description:

Percentage of subjects with at least 1/2048 serotype-specific pneumococcal OPA GMTs for serotype 7F determined in the blood samples of all subjects. The data was not collected as planned as the additional, more stringent qualification and validation of the improved mcOPA assays used in this study did not support 1/2048 for serotype 7F for the quantitation of a serum response and thus the established LLOQ was used for the mcOPA assay.

End point type	Secondary
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End point timeframe:

One month after vaccination

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[19]	0 ^[20]	0 ^[21]	
Units: percentage of subjects				
number (not applicable)				

Notes:

[19] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[20] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[21] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Subjects Achieving OPA GMTs With at Least Lower Limit of Quantification (LLOQ) 1 Month After Single Dose of 13vPnC Vaccine

End point title	Percentage of Subjects Achieving OPA GMTs With at Least Lower Limit of Quantification (LLOQ) 1 Month After Single Dose of 13vPnC Vaccine
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End point description:

Percentage of subjects achieving OPA GMTs with at least LLOQ for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) determined in blood samples of all subjects using mcOPA assay. Exact 2-sided CI based on observed proportion of subjects. LLOQ in titers for each serotype was: Pn001, 18; Pn003, 12; Pn004, 21; Pn005, 29; Pn06A, 37; Pn06B, 43; Pn7F, 210; Pn09V, 345; Pn014, 35; Pn18C, 31; Pn19A, 18; Pn19F, 48; Pn23F, 13. LOD established as lowest titer possible in assay, which was 8. OPA titers below LLOQ set to 0.5*LOD for analysis. Evaluable immunogenicity population. n= number of subjects with a determinate OPA antibody titer to the given serotype.

End point type	Post-hoc
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End point timeframe:

One month after vaccination

End point values	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	120 ^[22]	57 ^[23]	58 ^[24]	
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 4 (n= 117, 53, 55)	100 (96.9 to 100)	100 (93.3 to 100)	100 (93.5 to 100)	
Serotype 6B (n= 117, 57, 56)	100 (96.9 to 100)	100 (93.7 to 100)	100 (93.6 to 100)	
Serotype 9V (n= 116, 54, 55)	100 (96.9 to 100)	100 (93.4 to 100)	100 (93.5 to 100)	
Serotype 14 (n= 115, 54, 55)	100 (96.8 to 100)	100 (93.4 to 100)	100 (93.5 to 100)	
Serotype 18C (n= 117, 54, 57)	100 (96.9 to 100)	100 (93.4 to 100)	100 (93.7 to 100)	
Serotype 19F (n= 118, 57, 57)	98.3 (94 to 99.8)	100 (93.7 to 100)	98.2 (90.6 to 100)	
Serotype 23F (n= 118, 53, 56)	100 (96.9 to 100)	100 (93.3 to 100)	100 (93.6 to 100)	
Serotype 1 (n= 119, 56, 57)	100 (96.9 to 100)	100 (93.6 to 100)	100 (93.7 to 100)	

Serotype 3 (n= 118, 56, 58)	100 (96.9 to 100)	98.2 (90.4 to 100)	100 (93.8 to 100)	
Serotype 5 (n= 118, 55, 54)	99.2 (95.4 to 100)	96.4 (87.5 to 99.6)	100 (93.4 to 100)	
Serotype 6A (n= 117, 55, 55)	100 (96.9 to 100)	100 (93.5 to 100)	100 (93.5 to 100)	
Serotype 7F (n= 118, 56, 54)	100 (96.9 to 100)	100 (93.6 to 100)	100 (93.4 to 100)	
Serotype 19A (n= 116, 53, 54)	100 (96.9 to 100)	100 (93.3 to 100)	100 (93.4 to 100)	

Notes:

[22] - N= number of subjects analysed within a given treatment group.

[23] - N= number of subjects analysed within a given treatment group.

[24] - N= number of subjects analysed within a given treatment group.

Statistical analyses

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 4: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	6.7

Statistical analysis title	4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 4: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.5

Statistical analysis title	4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 4: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	6.6

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description: Serotype 6B: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	6.3

Statistical analysis title	6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description: Serotype 6B: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.4
upper limit	6.5

Statistical analysis title	6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6B: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.4

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.6

Statistical analysis title	9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.5

Statistical analysis title	9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 9V: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	6.5

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 14: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	6.6

Statistical analysis title	14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	6.5

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.6

Statistical analysis title	14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 14: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	6.5

Statistical analysis title	18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	6.3

Statistical analysis title	18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 18C: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	6.4

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 19F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	4.5

Statistical analysis title	19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 19F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	7.5

Statistical analysis title	19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 19F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	9.5

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	6.7

Statistical analysis title	23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 23F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.4

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 1: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	6.4

Statistical analysis title	23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 23F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	6.5

Statistical analysis title	1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 1: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.3

Statistical analysis title	1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 1: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	6.3

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 3: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	9.6

Statistical analysis title	3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 3: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	6.2

Statistical analysis title	3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 3: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.6
upper limit	4.5

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 5: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	11.3

Statistical analysis title	5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 5: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	5.6

Statistical analysis title	5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 5: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	-3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.5
upper limit	3.2

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 6A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC

Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.5

Statistical analysis title	6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.5

Statistical analysis title	6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 6A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	6.6

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
Statistical analysis description:	
Serotype 7F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.4

Statistical analysis title	7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 7F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	6.6

Statistical analysis title	7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
Statistical analysis description:	
Serotype 7F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.	
Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	6.7

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.7

Statistical analysis title	19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	6.6

Statistical analysis title	19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC
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Statistical analysis description:

Serotype 19A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

Comparison groups	7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	6.6

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs/SAEs: recorded from signing of informed consent form to completion of study (28-42 days post 13vPnC). Subjects recorded prespecified AEs in electronic diary: local reactions; systemic events; use of antipyretic medication (Day 1-Day 7 post 13vPnC).

Adverse event reporting additional description:

Adverse events (AEs) and Serious AEs were grouped by system organ class and summarized. AEs included solicited/unsolicited AEs collected in electronic diary (local and systemic reactions; systematic assessment) collected on case report form at each visit (nonsystematic assessment). LRs/SEs were assessed only for infant and toddler dose groups.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0.0
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Reporting groups

Reporting group title	13vPnC/13vPnC/13vPnC
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Reporting group description:

Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

Reporting group title	7vPnC/7vPnC/13vPnC
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Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.

Reporting group title	7vPnC/13vPnC/13vPnC
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Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.

Serious adverse events	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 130 (0.00%)	0 / 64 (0.00%)	0 / 64 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	13vPnC/13vPnC/13vPnC	7vPnC/7vPnC/13vPnC	7vPnC/13vPnC/13vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	82 / 130 (63.08%)	36 / 64 (56.25%)	39 / 64 (60.94%)
Injury, poisoning and procedural complications			

Radius fracture subjects affected / exposed occurrences (all)	0 / 130 (0.00%) 0	0 / 64 (0.00%) 0	1 / 64 (1.56%) 1
General disorders and administration site conditions Injection site erythema subjects affected / exposed occurrences (all)	1 / 130 (0.77%) 1	0 / 64 (0.00%) 0	0 / 64 (0.00%) 0
Fever >=38 degree C but <=39 degree C	Additional description: Subjects affected and occurrences for 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 Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all)	14 / 93 (15.05%) 14	14 / 49 (28.57%) 14	9 / 46 (19.57%) 9
Fever >39 degree C but <=40 degree C	Additional description: Subjects affected and occurrences for 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 Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	2 / 92 (2.17%) 2	2 / 43 (4.65%) 2	1 / 46 (2.17%) 1
Fever >40 degree C	Additional description: Subjects affected and occurrences for 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 Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	0 / 90 (0.00%) 0	0 / 43 (0.00%) 0	1 / 45 (2.22%) 1
Vomiting (Any)	Additional description: Subjects affected and occurrences for 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 Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	3 / 91 (3.30%) 3	4 / 44 (9.09%) 4	3 / 45 (6.67%) 3
Vomiting (Mild)	Additional description: Subjects affected and occurrences for 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 Event 0.0			

<p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p>	<p>3 / 91 (3.30%)</p> <p>3</p>	<p>4 / 44 (9.09%)</p> <p>4</p>	<p>3 / 45 (6.67%)</p> <p>3</p>
Diarrhea (Any)	Additional description: Subjects affected and occurrences for 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.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p>	<p>8 / 90 (8.89%)</p> <p>8</p>	<p>8 / 45 (17.78%)</p> <p>8</p>	<p>4 / 47 (8.51%)</p> <p>4</p>
Diarrhea (Mild)	Additional description: Subjects affected and occurrences for 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.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p>	<p>8 / 90 (8.89%)</p> <p>8</p>	<p>8 / 45 (17.78%)</p> <p>8</p>	<p>4 / 47 (8.51%)</p> <p>4</p>
Diarrhea (Moderate)	Additional description: Subjects affected and occurrences for 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.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p>	<p>1 / 90 (1.11%)</p> <p>1</p>	<p>0 / 43 (0.00%)</p> <p>0</p>	<p>0 / 45 (0.00%)</p> <p>0</p>
Fatigue (Any)	Additional description: Subjects affected and occurrences for 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.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p>	<p>42 / 103 (40.78%)</p> <p>42</p>	<p>28 / 54 (51.85%)</p> <p>28</p>	<p>15 / 48 (31.25%)</p> <p>15</p>
Fatigue (Mild)	Additional description: Subjects affected and occurrences for 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.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p>	<p>34 / 100 (34.00%)</p> <p>34</p>	<p>17 / 49 (34.69%)</p> <p>17</p>	<p>10 / 48 (20.83%)</p> <p>10</p>
Fatigue (Moderate)	Additional description: Subjects affected and occurrences for 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.			
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[11]</p> <p>occurrences (all)</p>	<p>16 / 96 (16.67%)</p> <p>16</p>	<p>15 / 49 (30.61%)</p> <p>15</p>	<p>7 / 46 (15.22%)</p> <p>7</p>
Fatigue (Severe)	Additional description: Subjects affected and occurrences for 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.		
<p>alternative dictionary used: Systemic Event 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[12]</p> <p>occurrences (all)</p>	<p>3 / 92 (3.26%)</p> <p>3</p>	<p>1 / 43 (2.33%)</p> <p>1</p>	<p>1 / 45 (2.22%)</p> <p>1</p>
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 130 (0.00%)	1 / 64 (1.56%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 130 (0.77%)	0 / 64 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 130 (0.00%)	1 / 64 (1.56%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Pain (Any)	Additional description: Subjects affected and occurrences for LRs 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.		
<p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[13]</p> <p>occurrences (all)</p>	<p>62 / 112 (55.36%)</p> <p>62</p>	<p>29 / 52 (55.77%)</p> <p>29</p>	<p>34 / 53 (64.15%)</p> <p>34</p>
Pain (Mild)	Additional description: Subjects affected and occurrences for LRs 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.		
<p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[14]</p> <p>occurrences (all)</p>	<p>55 / 109 (50.46%)</p> <p>55</p>	<p>25 / 51 (49.02%)</p> <p>25</p>	<p>29 / 51 (56.86%)</p> <p>29</p>

Pain (Moderate)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all)	17 / 95 (17.89%) 17	12 / 47 (25.53%) 12
Pain (Severe)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	1 / 90 (1.11%) 1	1 / 43 (2.33%) 1
Swelling (Any)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	40 / 101 (39.60%) 40	20 / 48 (41.67%) 20
Swelling (Mild)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	27 / 96 (28.13%) 27	17 / 48 (35.42%) 17
Swelling (Moderate)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all)	24 / 97 (24.74%) 24	9 / 44 (20.45%) 9
Swelling (Severe)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0 alternative assessment type: Systematic		

subjects affected / exposed ^[20]	0 / 90 (0.00%)	1 / 43 (2.33%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Redness (Any)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[21]	51 / 105 (48.57%)	27 / 50 (54.00%)	23 / 50 (46.00%)
occurrences (all)	51	27	23
Redness (Mild)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[22]	39 / 101 (38.61%)	20 / 49 (40.82%)	18 / 48 (37.50%)
occurrences (all)	39	20	18
Redness (Moderate)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[23]	21 / 95 (22.11%)	14 / 45 (31.11%)	8 / 47 (17.02%)
occurrences (all)	21	14	8
Redness (Severe)	Additional description: Subjects affected and occurrences for LRs 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 Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[24]	0 / 90 (0.00%)	1 / 43 (2.33%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	1 / 130 (0.77%)	0 / 64 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	2 / 130 (1.54%)	0 / 64 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Ear infection			

subjects affected / exposed	0 / 130 (0.00%)	1 / 64 (1.56%)	1 / 64 (1.56%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	1 / 130 (0.77%)	1 / 64 (1.56%)	1 / 64 (1.56%)
occurrences (all)	1	1	1
Nasopharyngitis			
subjects affected / exposed	3 / 130 (2.31%)	0 / 64 (0.00%)	0 / 64 (0.00%)
occurrences (all)	3	0	0
Pharyngitis			
subjects affected / exposed	2 / 130 (1.54%)	0 / 64 (0.00%)	1 / 64 (1.56%)
occurrences (all)	2	0	1
Rhinitis			
subjects affected / exposed	0 / 130 (0.00%)	1 / 64 (1.56%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	2 / 130 (1.54%)	1 / 64 (1.56%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Urinary tract infection			
subjects affected / exposed	1 / 130 (0.77%)	0 / 64 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Varicella			
subjects affected / exposed	2 / 130 (1.54%)	0 / 64 (0.00%)	1 / 64 (1.56%)
occurrences (all)	2	0	1
Viral infection			
subjects affected / exposed	2 / 130 (1.54%)	1 / 64 (1.56%)	0 / 64 (0.00%)
occurrences (all)	2	1	0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no

exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported