Clinical trial results:
A Phase 4, Open-label Trial Describing The Safety, Tolerability, And Immunogenicity Of The 13 Valent Pneumococcal Conjugate Vaccine (13vPnC) In Preterm Compared To Term Infants

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2009-017332-41
Trial protocol	ES PL
Global end of trial date	23 January 2014

Results information

Result version number	v2 (current)
This version publication date	28 July 2016
First version publication date	02 August 2015
Version creation reason	• Correction of full data set reporting periods and duplicate AEs in their data

Trial information

Trial identification

Sponsor protocol code	B1851037

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01193335
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer CT.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer CT.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000036-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 July 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to describe the safety, tolerability, and immunogenicity of a 2,3,4 and 12 month schedule of the 13-valent pneumococcal conjugate vaccine when given to preterm infants with concomitant vaccines, compared to infants born at term.There will be a follow-up phase to assess the persistence of the antibody response at 24 and 36 months of age.

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	19 October 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 100
Country: Number of subjects enrolled	Spain: 100
Worldwide total number of subjects	200
EEA total number of subjects	200

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)	200

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

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study started on 19 October 2010. A total of 200 subjects were enrolled in study 100 were from Poland and 100 were from Spain. All 200 subjects completed the 3-dose infant series of vaccinations and 196 subjects received the toddler dose and continued through the study through the post–toddler dose blood draw. The study completed on 23 Jan 2014.

Period 1

Period 1 title	Infant Series
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Group 1 (Preterm Infant)

Arm description:

Preterm infant subjects (gestational age [GA] less than [<] 37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA greater than or equal to [>=] 32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).

Arm type	Active comparator
Investigational medicinal product name	13vPnC Group 1 (Preterm Infant)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

13vPnC was administered at a dose of 0.5 milliliter (mL) at 2, 3, 4 months of age (infant series).

Arm title	13vPnC Group 2 (Term Infant)

Arm description:

Term infant subjects (GA >=37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series).

Arm type	Active comparator
Investigational medicinal product name	13vPnC Group 2 (Term Infant)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

13vPnC was administered at a dose of 0.5 mL at 2, 3, 4 months of age (infant series).

Number of subjects in period 1	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)
Started	100	100
Completed	100	100

Period 2	
Period 2 title	After Infant Series
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Group 1 (Preterm Infant)

Arm description:

Preterm infant subjects (GA <37 weeks) received single dose of 13-valent pneumococcal conjugate vaccine (13vPnC) at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC Group 2 (Term Infant)

Arm description:

Term infant subjects (GA >=37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)
Started	100	100
Completed	99	97
Not completed	1	3
No longer met eligibility criteria	-	1
Lost to follow-up	1	2

Period 3

Period 3 title	Toddler Dose
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Group 1 (Preterm Infant)

Arm description:

Preterm infant subjects (GA <37 weeks) received dose of 13vPnC at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).

Arm type	Active comparator
Investigational medicinal product name	13vPnC Group 1 (Preterm Infant)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

13vPnC was administered at a dose of 0.5 milliliter (mL) at 2, 3, 4 months of age (infant series) and at 1 2 months of age (toddler dose).

Arm title	13vPnC Group 1 (Term Infant)

Arm description:

Term infant subjects (GA >=37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose).

Arm type	Active comparator
Investigational medicinal product name	13vPnC Group 2 (Term Infant)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

13vPnC was administered at a dose of 0.5 mL at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose).

Number of subjects in period 3	13vPnC Group 1 (Preterm Infant)	13vPnC Group 1 (Term Infant)
Started	99	97
Completed	99	97

Period 4	
Period 4 title	1-Year Follow-up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Group 1 (Preterm Infant)

Arm description:

Preterm infant subjects (GA <37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC Group 2 (Term Infant)

Arm description:

Term infant subjects (GA >=37 weeks) received single dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)
Started	99	97
Completed	88	88
Not completed	11	9
No longer willing to participate	7	9
Lost to follow-up	4	-

Period 5	
Period 5 title	2-Year Follow-up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Group 2 (Term Infant)

Arm description:

Term infant subjects (GA >=37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC Group 1 (Preterm Infant)

Arm description:
Preterm infants (GA <37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 5	13vPnC Group 2 (Term Infant)	13vPnC Group 1 (Preterm Infant)
Started	88	88
Completed	80	81
Not completed	8	7
No longer met eligibility criteria	2	2
No longer willing to participate	6	5

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC Group 1 (Preterm Infant)
Reporting group description:	
Preterm infant subjects (gestational age [GA] less than [<] 37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA greater than or equal to [>=] 32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).	
Reporting group title	13vPnC Group 2 (Term Infant)
Reporting group description:	
Term infant subjects (GA >=37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series).	

Reporting group values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)	Total
Number of subjects	100	100	200
Age categorical			
Units: Subjects			
Age Continuous			
Units: months			
arithmetic mean	1.8	1.5	
standard deviation	± 0.6	± 0.5	-
Gender, Male/Female			
Units: participants			
Male	52	45	97
Female	48	55	103

End points

End points reporting groups

Reporting group title	13vPnC Group 1 (Preterm Infant)
Reporting group description:	
Preterm infant subjects (gestational age [GA] less than [<] 37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA greater than or equal to [>=] 32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).	
Reporting group title	13vPnC Group 2 (Term Infant)
Reporting group description:	
Term infant subjects (GA >=37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series).	
Reporting group title	13vPnC Group 1 (Preterm Infant)
Reporting group description:	
Preterm infant subjects (GA <37 weeks) received single dose of 13-valent pneumococcal conjugate vaccine (13vPnC) at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).	
Reporting group title	13vPnC Group 2 (Term Infant)
Reporting group description:	
Term infant subjects (GA >=37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series).	
Reporting group title	13vPnC Group 1 (Preterm Infant)
Reporting group description:	
Preterm infant subjects (GA <37 weeks) received dose of 13vPnC at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).	
Reporting group title	13vPnC Group 1 (Term Infant)
Reporting group description:	
Term infant subjects (GA >=37 weeks) received single dose of 13vPnC at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose).	
Reporting group title	13vPnC Group 1 (Preterm Infant)
Reporting group description:	
Preterm infant subjects (GA <37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).	
Reporting group title	13vPnC Group 2 (Term Infant)
Reporting group description:	
Term infant subjects (GA >=37 weeks) received single dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series).	
Reporting group title	13vPnC Group 2 (Term Infant)
Reporting group description:	
Term infant subjects (GA >=37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series).	
Reporting group title	13vPnC Group 1 (Preterm Infant)
Reporting group description:	
Preterm infants (GA <37 weeks) received 13vPnC at 2, 3, 4 months of age (infant series). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).	
Subject analysis set title	13vPnC Group 1A
Subject analysis set type	Full analysis
Subject analysis set description:	
Preterm infant subjects with GA >=32 weeks and <37 weeks received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose).	
Subject analysis set title	13vPnC Group 1B
Subject analysis set type	Full analysis

Subject analysis set description:

Preterm infant subjects with GA >=29 weeks and <32 weeks received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose).

Subject analysis set title	13vPnC Group 1C
Subject analysis set type	Full analysis

Subject analysis set description:

Preterm subjects with GA <29 weeks received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose).

Subject analysis set title	13vPnC Group 1 (Preterm Infant)
Subject analysis set type	Full analysis

Subject analysis set description:

Preterm infant subjects (GA <37 weeks) received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and at 12 months of age (toddler dose). Preterm infant group was subdivided into Group 1A (GA >=32 weeks and <37 weeks), Group 1B (GA >=29 weeks and <32 weeks) and Group 1C (GA <29 weeks).

Primary: Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=) 0.35 Microgram per Milliliter (mcg/mL) 1 Month After Infant Series

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=) 0.35 Microgram per Milliliter (mcg/mL) 1 Month After Infant Series

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95 percent (%) confidence interval (CI) for the 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) were presented. Exact 2-sided CI based on the observed proportion of subjects. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively. Evaluable infant immunogenicity population included eligible subjects who received all the assigned vaccinations (Infant Dose 1, 2 and 3), had blood drawn within required time frames, had at least 1 valid and determinate assay result for the proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	98		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n=99, 97)	96.97 (91.4 to 99.37)	98.97 (94.39 to 99.97)		
6B (n=99, 97)	72.73 (62.85 to 81.2)	87.63 (79.39 to 93.44)		
9V (n=99, 97)	96.97 (91.4 to 99.37)	96.91 (91.23 to 99.36)		
14 (n=99, 97)	100 (96.34 to 100)	97.94 (92.75 to 99.75)		
18C (n=99, 97)	96.97 (91.4 to 99.37)	94.85 (88.38 to 98.31)		
19F (n=99, 97)	98.99 (94.5 to 99.97)	98.97 (94.39 to 99.97)		

23F (n=99, 97)	85.86 (77.41 to 92.05)	92.78 (85.7 to 97.05)		
1 (n=99, 97)	93.94 (87.27 to 97.74)	95.88 (89.78 to 98.87)		
3 (n=99, 97)	85.86 (77.41 to 92.05)	90.72 (83.12 to 95.67)		
5 (n=99, 97)	71.72 (61.78 to 80.31)	90.72 (83.12 to 95.67)		
6A (n=98, 97)	82.65 (73.69 to 89.56)	94.85 (88.38 to 98.31)		
7F (n=99, 97)	98.99 (94.5 to 99.97)	98.97 (94.39 to 99.97)		
19A (n=99, 97)	98.99 (94.5 to 99.97)	98.97 (94.39 to 99.97)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.65
upper limit	2.88

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.4
upper limit	-3.21

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.84
upper limit	6.05

Statistical analysis title	Serotype 14
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	2.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.71
upper limit	7.25

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	2.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.09
upper limit	8.89

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.54
upper limit	4.68

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-6.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.19
upper limit	1.89

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.07
upper limit	4.86

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-4.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.4
upper limit	4.39

Statistical analysis title	Serotype 5
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-19

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.1
upper limit	-7.16

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-12.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.66
upper limit	-3.26

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.54
upper limit	4.68

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.54
upper limit	4.68

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series

End point description:

Antibody geometric mean concentration (GMC) 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable infant immunogenicity population. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively.

End point type	Primary

End point timeframe:

1 month after the infant series

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	98		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n=99, 97)	1.96 (1.67 to 2.31)	2.46 (2.04 to 2.97)		
6B (n=99, 97)	0.73 (0.55 to 0.97)	1.3 (1 to 1.67)		
9V (n=99, 97)	1.26 (1.08 to 1.47)	1.7 (1.45 to 2)		
14 (n=99, 97)	7.48 (6.23 to 8.99)	6.08 (4.82 to 7.67)		
18C (n=99, 97)	1.93 (1.66 to 2.24)	1.93 (1.62 to 2.29)		
19F (n=99, 97)	2.21 (1.89 to 2.58)	3.05 (2.62 to 3.55)		
23F (n=99, 97)	0.86 (0.69 to 1.07)	1.36 (1.1 to 1.68)		
1 (n=99, 97)	1.26 (1.06 to 1.48)	1.79 (1.5 to 2.13)		

3 (n=99, 97)	0.83 (0.7 to 0.98)	0.86 (0.75 to 1)		
5 (n=99, 97)	0.56 (0.44 to 0.7)	1.03 (0.87 to 1.22)		
6A (n=98, 97)	1.22 (0.98 to 1.53)	2.01 (1.65 to 2.46)		
7F (n=99, 97)	2.14 (1.81 to 2.53)	3.02 (2.63 to 3.48)		
19A (n=99, 97)	2.85 (2.44 to 3.33)	3.35 (2.85 to 3.94)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.02

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.82

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.93

Statistical analysis title	Serotype 14
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.65

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.25

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.9

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.86

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.89

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.19

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.72

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	0.82

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.88

Statistical analysis title	Serotype 19 A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.07

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Dose 1 Infant Series

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Dose 1 Infant Series[1]

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurts if gently touched with no crying); Moderate (hurts if gently touched with crying); Severe (causes limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population for Dose 1 infant series: all subjects who received13vPnC Dose 1. Here 'N' (number of subjects analyzed)= subjects reporting yes for at least 1 day or no for all days for any local reaction.'n'=subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Primary

End point timeframe:

Within 7 days after Dose 1 of the infant series

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	92		
Units: percentage of subjects				
number (not applicable)				
Tenderness- Any (n=94, 88)	48.9	42		
Tenderness- Mild (n=93, 88)	46.2	31.8		
Tenderness- Moderate (n=90, 85)	17.8	16.5		
Tenderness- Severe (n=86, 85)	0	0		

Swelling- Any (n=94, 89)	39.4	29.2		
Swelling- Mild (n=91, 89)	37.4	28.1		
Swelling- Moderate (n=91, 85)	8.8	8.2		
Swelling- Severe (n=86, 85)	0	0		
Redness- Any (n=92, 87)	33.7	29.9		
Redness- Mild (n=90, 87)	32.2	28.7		
Redness- Moderate (n=88, 85)	3.4	4.7		
Redness- Severe (n=86, 85)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Dose 2 Infant Series

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Dose 2 Infant Series[2]

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurts if gently touched with no crying); Moderate (hurts if gently touched with crying); Severe (causes limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population for Dose 2 infant series: all subjects who received 13vPnC Dose 2.Here 'N' (number of subjects analyzed)=subjects reporting yes for at least 1 day or no for all days for any local reaction.'n'=subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Primary

End point timeframe:

Within 7 days after Dose 2 of the infant series

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	89		
Units: percentage of subjects				
number (not applicable)				
Tenderness- Any (n=85, 88)	48.2	38.6		
Tenderness- Mild (n=85, 84)	43.5	31		
Tenderness- Moderate (n=77, 83)	14.3	15.7		
Tenderness- Severe (n=73, 77)	0	1.3		
Swelling- Any (n=84, 82)	35.7	42.7		
Swelling- Mild (n=83, 82)	33.7	42.7		
Swelling- Moderate (n=75, 76)	8	2.6		
Swelling- Severe (n=73, 76)	0	0		
Redness- Any (n=82, 82)	28	40.2		
Redness- Mild (n=82, 82)	28	37.8		
Redness- Moderate (n=73, 76)	2.7	2.6		
Redness- Severe (n=73, 76)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Dose 3 Infant Series

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Dose 3 Infant Series[3]

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurts if gently touched with no crying); Moderate (hurts if gently touched with crying); Severe (causes limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population for Dose 3 infant series: all subjects who received 13vPnC Dose 3.Here 'N' (number of subjects analyzed)=subjects reporting yes for at least 1 day or no for all days for any local reaction.'n'=subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Primary

End point timeframe:

Within 7 days after Dose 3 of the infant series

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	90		
Units: percentage of subjects				
number (not applicable)				
Tenderness- Any (n=82, 84)	39	28.6		
Tenderness- Mild (n=81, 84)	35.8	26.2		
Tenderness- Moderate (n=75, 78)	9.3	5.1		
Tenderness- Severe (n=73, 77)	0	0		
Swelling- Any (n=83, 85)	30.1	41.2		
Swelling- Mild (n=82, 85)	26.8	41.2		
Swelling- Moderate (n=75, 79)	5.3	5.1		
Swelling- Severe (n=73, 77)	0	0		
Redness- Any (n=82, 87)	32.9	46		
Redness- Mild (n=82, 87)	32.9	46		
Redness- Moderate (n=74, 79)	1.4	3.8		
Redness- Severe (n=73, 77)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Toddler Dose

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions Within 7 Days After Toddler Dose[4]

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurts if gently touched with no crying); Moderate (hurts if gently touched with crying); Severe (causes limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population for Toddler Dose: all subjects who received 13vPnC Toddler Dose. Here 'N' (number of subjects analyzed)=subjects reporting yes for at least 1 day or no for all days for any local reaction.'n'=subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Primary

End point timeframe:

Within 7 days after the toddler dose

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	88		
Units: percentage of subjects				
number (not applicable)				
Tenderness- Any (n=86, 85)	69.8	55.3		
Tenderness- Mild (n=86, 85)	66.3	51.8		
Tenderness- Moderate (n=77, 70)	20.8	11.4		
Tenderness- Severe (n=74, 69)	2.7	0		
Swelling- Any (n=81, 80)	43.2	35		
Swelling- Mild (n=80, 79)	38.8	32.9		
Swelling- Moderate (n=76, 74)	13.2	9.5		
Swelling- Severe (n=74, 69)	1.4	0		
Redness- Any (n=85, 83)	51.8	49.4		
Redness- Mild (n=85, 83)	51.8	48.2		
Redness- Moderate (n=75, 75)	6.7	10.7		
Redness- Severe (n=74, 69)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Dose 1 Infant Series

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Dose 1 Infant Series[5]

End point description:

Systemic events (fever >=38 degrees Celsius [C], decreased appetite, increased sleep, and irritability or decreased sleep) and use of antipyretic medication were reported using an electronic diary. Decreased appetite was scaled as Any; Mild (loss of appetite but no decreased oral intake); Moderate (decreased oral intake); Severe (refusal to feed). Increased sleep was scaled as Any; Mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (disabling not interested in usual daily activity). Irritability or decreased sleep was scaled as Any; Mild (easily consolable); Moderate (requiring increased attention); Severe (inconsolable; crying that cannot be comforted). Subjects may be represented in more than 1 category. Safety population. Here N = number of subjects analyzed and n=subjects reporting yes for at least 1 day or no for all days for specified event for each group, respectively.

End point type	Primary

End point timeframe:

Within 7 days after Dose 1 of the infant series

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	99		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 degrees C (n=86, 88)	11.6	13.6		
Fever >=38 degrees C, =<39 degrees C (n=86, 88)	10.5	13.6		
Fever >=39 degrees C, =<40 degrees C (n=86, 85)	1.2	0		
Fever >40 degrees C (n=86, 85)	0	0		
Decreased Appetite- Any (n=92, 89)	60.9	41.6		
Decreased Appetite- Mild (n=91, 88)	54.9	35.2		
Decreased Appetite- Moderate (n=88, 87)	20.5	17.2		
Decreased Appetite- Severe (n=86, 85)	1.2	0		
Increased Sleep- Any (n=96, 95)	67.7	69.5		
Increased Sleep- Mild (n=96, 93)	60.4	61.3		
Increased Sleep- Moderate (n=87, 88)	29.9	30.7		
Increased Sleep- Severe (n=86, 85)	2.3	2.4		
Irritability or Decreased Sleep- Any (n=95, 97)	84.2	82.5		
Irritability or Decreased Sleep- Mild (n=93, 95)	77.4	69.5		
Irritability or Decreased Sleep-Moderate (n=92, 91	43.5	47.3		
Irritability or Decreased Sleep- Severe (n=86, 85)	8.1	5.9		
Use of Antipyretic Medication (n=90, 90)	24.4	24.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Dose 2 Infant Series

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Dose 2 Infant Series[6]

End point description:

Systemic events (fever >=38 degrees Celsius [C], decreased appetite, increased sleep, and irritability or decreased sleep) and use of antipyretic medication were reported using an electronic diary. Decreased appetite was scaled as Any; Mild (loss of appetite but no decreased oral intake); Moderate (decreased oral intake); Severe (refusal to feed). Increased sleep was scaled as Any; Mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (disabling not interested in usual daily activity). Irritability or decreased sleep was scaled as Any; Mild (easily consolable); Moderate (requiring increased attention); Severe (inconsolable; crying that cannot be comforted). Subjects may be represented in more than 1 category. Safety population for Dose 2 infant series: all subjects who received 13vPnC Dose 2. Here 'N' (number of subjects analyzed)=subjects reporting yes for at least 1 day or no for all days for any event and 'n'=p

End point type	Primary

End point timeframe:

Within 7 days after Dose 2 of the infant series

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	96		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 degrees C (n=79, 79)	27.8	31.6		
Fever >=38 degrees C, =<39 degrees C (n=79, 79)	27.8	30.4		
Fever >=39 degrees C, =<40 degrees C (n=73, 76)	0	1.3		
Fever >40 degrees C (n=73, 76)	0	0		
Decreased Appetite- Any (n=89, 84)	61.8	46.4		
Decreased Appetite- Mild (n=88, 84)	55.7	41.7		
Decreased Appetite- Moderate (n=79, 78)	25.3	19.2		
Decreased Appetite- Severe (n=73, 76)	1.4	0		
Increased Sleep- Any (n=85, 89)	74.1	64		
Increased Sleep- Mild (n=83, 88)	69.9	59.1		
Increased Sleep- Moderate (n=78, 78)	34.6	29.5		
Increased Sleep- Severe (n=73, 76)	2.7	1.3		
Irritability or Decreased Sleep- Any (n=95, 95)	89.5	77.9		
Irritability or Decreased Sleep- Mild (n=90, 92)	81.1	71.7		
Irritability or Decreased Sleep-Moderate (n=85, 86	64.7	44.2		
Irritability or Decreased Sleep- Severe (n=74, 76)	17.6	2.6		
Use of Antipyretic Medication (n=84, 83)	48.8	45.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Dose 3 Infant Series

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Dose 3 Infant Series[7]

End point description:

Systemic events (fever >=38 degrees Celsius [C], decreased appetite, increased sleep, and irritability or decreased sleep) and use of antipyretic medication were reported using an electronic diary. Decreased appetite was scaled as Any; Mild (loss of appetite but no decreased oral intake); Moderate (decreased oral intake); Severe (refusal to feed). Increased sleep was scaled as Any; Mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (disabling not interested in usual daily activity). Irritability or decreased sleep was scaled as Any; Mild (easily consolable); Moderate (requiring increased attention); Severe (inconsolable; crying that cannot be comforted). Subjects may be represented in more than 1 category. Safety population. N =number of subjects analyzed and n=subjects reporting yes for at least 1 day or no for all days for specified event for each group, respectively.

End point type	Primary

End point timeframe:

Within 7 days after Dose 3 of the infant series

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	95		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 degrees C (n=79, 81)	27.8	30.9		
Fever >=38 degrees C, =<39 degrees C (n=78, 81)	26.9	30.9		
Fever >=39 degrees C, =<40 degrees C (n=75, 78)	1.3	2.6		
Fever >40 degrees C (n=74, 77)	0	0		
Decreased Appetite- Any (n=82, 84)	48.8	47.6		
Decreased Appetite- Mild (n=82, 84)	36.6	46.4		
Decreased Appetite- Moderate (n=74, 79)	17.6	16.5		
Decreased Appetite- Severe (n=74, 77)	1.4	1.3		
Increased Sleep- Any (n=88, 88)	52.3	58		
Increased Sleep- Mild (n=88, 87)	48.9	51.7		
Increased Sleep- Moderate (n=77, 80)	16.9	20		
Increased Sleep- Severe (n=73, 77)	1.4	1.3		

Irritability or Decreased Sleep- Any (n=92, 95)	79.3	81.1		
Irritability or Decreased Sleep- Mild (n=90, 91)	72.2	74.7		
Irritability or Decreased Sleep-Moderate (n=80,87)	33.8	35.6		
Irritability or Decreased Sleep- Severe (n=74, 78)	6.8	6.4		
Use of Antipyretic Medication (n=84, 81)	40.5	38.3		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Toddler Dose

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events Within 7 Days After Toddler Dose[8]

End point description:

Systemic events (fever >=38 degrees Celsius [C], decreased appetite, increased sleep, and irritability or decreased sleep) and use of antipyretic medication were reported using an electronic diary. Decreased appetite was scaled as Any; Mild (loss of appetite but no decreased oral intake); Moderate (decreased oral intake); Severe (refusal to feed). Increased sleep was scaled as Any; Mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (disabling not interested in usual daily activity). Irritability or decreased sleep was scaled as Any; Mild (easily consolable); Moderate (requiring increased attention); Severe (inconsolable; crying that cannot be comforted). Subjects may be represented in more than 1 category. Safety population for Toddler Dose: all subjects who received 13vPnC Toddler Dose. N=number of subjects analyzed, n=subjects reporting yes for at least 1 day or no for all days for specified event for each group.

End point type	Primary

End point timeframe:

Within 7 days after the toddler dose

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this outcome measure.

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	92		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 degrees C (n= 80, 78)	28.8	43.6		
Fever >=38 degrees C, =<39 degrees C (n=80, 77)	27.5	42.9		
Fever >=39 degrees C, =<40 degrees C (n=74, 71)	1.4	4.2		
Fever >40 degrees C (n=74, 70)	0	1.4		
Decreased Appetite- Any (n=87, 86)	57.5	60.5		
Decreased Appetite- Mild (n=86, 84)	50	56		
Decreased Appetite- Moderate (n=78, 73)	25.6	23.3		
Decreased Appetite- Severe (n=75, 69)	1.3	1.4		

Increased Sleep- Any (n=83, 86)	57.8	65.1		
Increased Sleep- Mild (n=82, 84)	53.7	59.5		
Increased Sleep- Moderate (n=76, 74)	18.4	24.3		
Increased Sleep- Severe (n=74, 70)	0	2.9		
Irritability or Decreased Sleep- Any (n=90, 91)	84.4	80.2		
Irritability or Decreased Sleep- Mild (n=90, 89)	74.4	76.4		
Irritability or Decreased Sleep-Moderate (n=78,80)	44.9	45		
Irritability or Decreased Sleep- Severe (n=76, 69)	6.6	4.3		
Use of Antipyretic Medication (n=82, 79)	48.8	50.6		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): Infant Series

End point title	Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): Infant Series

End point description:

An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly.

End point type	Primary

End point timeframe:

Dose 1 up to 1 month after Dose 3 (infant series)

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100	100		
Units: percentage of subjects				
number (not applicable)				
AEs	59	55		
SAEs	14	5		

Statistical analyses

Statistical analysis title	Subject with AEs

Statistical analysis description:

AEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term

	Infant)
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.668
Method	Fisher exact

Statistical analysis title	Subject with SAEs
Statistical analysis description:	
SAEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.051
Method	Fisher exact

Primary: Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): After Infant Series

End point title	Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): After Infant Series
End point description:	
An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Safety population for infant series included all subjects who received at least 1 dose of 13vPnC during infant series.	
End point type	Primary
End point timeframe:	
1 Month after Dose 3 of the infant series up to toddler dose	

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100	100		
Units: percentage of subjects				
number (not applicable)				
AEs	18	15		
SAEs	8	9		

Statistical analyses

Statistical analysis title	Subjects with AEs

Statistical analysis description:

AEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.704
Method	Fisher exact

Statistical analysis title	Subjects with SAEs

Statistical analysis description:

SAEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.99
Method	Fisher exact

Primary: Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): Toddler Dose

End point title	Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): Toddler Dose

End point description:

An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly.

End point type	Primary

End point timeframe:

Toddler dose up to 1 Month after toddler dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	97		
Units: percentage of subjects				
number (not applicable)				
AEs	31.3	26.8		
SAEs	2	1		

Statistical analyses

Statistical analysis title	Subjects with AEs
Statistical analysis description:	
AEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.531
Method	Fisher exact

Statistical analysis title	Subject with SAEs
Statistical analysis description:	
SAEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.99
Method	Fisher exact

Primary: Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): 1-Year Follow-up After Toddler Dose

End point title	Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): 1-Year Follow-up After Toddler Dose
End point description:	
An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Safety population for infant series included all subjects who received at least 1 dose of 13vPnC during infant series.	
End point type	Primary
End point timeframe:	
1 month after toddler dose up to 1-year follow-up	

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	97		
Units: percentage of subjects				
number (not applicable)				
AEs	15.2	8.2		
SAEs	13.1	8.2		

Statistical analyses

Statistical analysis title	Subject with AEs
Statistical analysis description: AEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.183
Method	Fisher exact

Statistical analysis title	Subject with SAEs
Statistical analysis description: SAEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.357
Method	Fisher exact

Primary: Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): 2-Year Follow-up After Toddler Dose

End point title	Percentage of Subjects With Adverse Events (AEs) or Serious Adverse Events (SAEs): 2-Year Follow-up After Toddler Dose
End point description: An AE was any untoward medical occurrence in a subject who received vaccine without regard to possibility of causal relationship. SAE: an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial/prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly.Safety population for 2-year follow-up after toddler dose included all subjects who received 13vPnC toddler dose and had safety data available during specified follow-up period.	
End point type	Primary

End point timeframe:

1-year follow-up after toddler dose to 2-year follow-up after toddler dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: percentage of subjects				
number (not applicable)				
AEs	8	10.2		
SAEs	6.8	9.1		

Statistical analyses

Statistical analysis title	Subject with AEs

Statistical analysis description:

AEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.794
Method	Fisher exact

Statistical analysis title	Subject with SAEs

Statistical analysis description:

SAEs: Two sided Fisher exact test, was used to calculate difference between vaccine groups.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.782
Method	Fisher exact

Secondary: Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From Toddler Pre-Dose to 1 Month After Toddler Dose

End point title	Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From Toddler Pre-Dose to 1 Month After Toddler Dose

End point description:

GMFR for the 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) from before 13vPnC toddler dose to 1 month after 13vPnC toddler dose were computed using the logarithmically transformed assay results. CIs for GMFR were back transformations of confidence levels based on the Student t distribution for the mean logarithm of the fold rises. GMFRs were calculated using all subjects with available data from both before 13vPnC toddler dose and after 13vPnC toddler dose blood draws. Safety population for 1-year follow-up after toddler dose included all subjects who received 13vPnC toddler dose and had safety data available during specified follow-up period. Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate IgG antibody concentration to the given serotype for each arm, respectively.

End point type	Secondary

End point timeframe:

Before 13vPnC Toddler Dose (pre-vaccination), 1 month after 13vPnC Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: fold rise				
geometric mean (confidence interval 95%)				
4 (n= 83, 85)	8.14 (6.61 to 10.04)	9.61 (7.77 to 11.88)		
6B (n=80, 85)	9.46 (7.81 to 11.45)	7.61 (6.31 to 9.18)		
9V (n=83, 85)	5.85 (5.05 to 6.78)	4.92 (4.22 to 5.74)		
14 (n=83, 85)	4.5 (3.76 to 5.38)	4.65 (3.82 to 5.65)		
18C (n=83, 85)	7.36 (6.29 to 8.61)	9.14 (7.61 to 10.98)		
19F (n=83, 85)	10.82 (8.88 to 13.17)	12.31 (9.77 to 15.51)		
23F (n=79, 83)	10.11 (8.13 to 12.57)	10.15 (8.32 to 12.39)		
1 (n=83, 85)	8.41 (6.94 to 10.2)	9.98 (8.18 to 12.17)		
3 (n=81, 84)	7.61 (5.79 to 10.01)	5.23 (4.22 to 6.49)		
5 (n=80, 85)	3.47 (3.04 to 3.97)	3.46 (2.93 to 4.09)		
6A (n=83, 85)	10.52 (8.75 to 12.64)	7.72 (6.18 to 9.65)		
7F (n=83, 85)	5.81 (5.12 to 6.61)	6.07 (5.16 to 7.13)		
19A (n=83, 85)	6.45 (5.39 to 7.72)	5.59 (4.53 to 6.9)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.14

Statistical analysis title	Serotype 6B

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.62

Statistical analysis title	Serotype 9V

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1.19

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.47

Statistical analysis title	Serotype 14

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.26

Statistical analysis title	Serotype 18C

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.02

Statistical analysis title	Serotype 19F

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for

the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.19

Statistical analysis title	Serotype 23F

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.33

Statistical analysis title	Serotype 1

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.11

Statistical analysis title	Serotype 3
Statistical analysis description:	
GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	2.05

Statistical analysis title	Serotype 5
Statistical analysis description:	
GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.24

Statistical analysis title	Serotype 6A
Statistical analysis description:	
GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.82

Statistical analysis title	Serotype 7F

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.18

Statistical analysis title	Serotype 19A

Statistical analysis description:

GMFR ratio was calculated by back transforming the GMFR difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on Student t distribution for the ratio difference of logarithms of the measures (Group 1 – Group 2).

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMFR Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.52

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level >=0.35 mcg/mL 1 Month After Infant Series: Group 1A, 1B, 1C

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level >=0.35 mcg/mL 1 Month After Infant Series: Group 1A, 1B, 1C

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95 % CI for the 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) were presented. Exact 2-sided CI based on the observed proportion of subjects. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively. Evaluable infant immunogenicity population included eligible subjects who received all the assigned vaccinations (Infant Dose 1, 2 and 3), had blood drawn within required time frames, had at least 1 valid and determinate assay result for the proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 Month After Infant Series

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	50	25	
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n=24, 50, 25)	100 (85.75 to 100)	96 (86.29 to 99.51)	96 (79.65 to 99.9)	
6B (n=24, 50, 25)	79.17 (57.85 to 92.87)	72 (57.51 to 83.77)	68 (46.5 to 85.05)	
9V (n=24, 50, 25)	95.83 (78.88 to 99.89)	98 (89.35 to 99.95)	96 (79.65 to 99.9)	
14 (n=24, 50, 25)	100 (85.75 to 100)	100 (92.89 to 100)	100 (86.28 to 100)	
18C (n=24, 50, 25)	100 (85.75 to 100)	94 (83.45 to 98.75)	100 (86.28 to 100)	
19F (n=24, 50, 25)	100 (85.75 to 100)	98 (89.35 to 99.95)	100 (86.28 to 100)	
23F (n=24, 50, 25)	91.67 (73 to 98.97)	80 (66.28 to 89.97)	92 (73.97 to 99.02)	
1 (n=24, 50, 25)	100 (85.75 to 100)	92 (80.77 to 97.78)	92 (73.97 to 99.02)	
3 (n=24, 50, 25)	87.5 (67.64 to 97.34)	86 (73.26 to 94.18)	84 (63.92 to 95.46)	
5 (n=24, 50, 25)	79.17 (57.85 to 92.87)	66 (51.23 to 78.79)	76 (54.87 to 90.64)	
6A (n=24, 49, 25)	95.83 (78.88 to 99.89)	81.63 (67.98 to 91.24)	72 (50.61 to 87.93)	
7F (n=24, 50, 25)	100 (85.75 to 100)	98 (89.35 to 99.95)	100 (86.28 to 100)	
19A (n=24, 50, 25)	100 (85.75 to 100)	98 (89.35 to 99.95)	100 (86.28 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥0.35 mcg/mL 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥0.35 mcg/mL 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% CI for the 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) were presented. Exact 2-sided CI based on the observed proportion of subjects. Here 'n' signifies subjects with a determinate IgG antibody concentration to the given serotype for each arm, respectively. Evaluable Toddler Immunogenicity Population included eligible subjects who received all the assigned vaccinations (Infant Dose 1, 2, 3 and toddler dose), had blood drawn within required time frames, had at least 1 valid and determinate assay result for the proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n= 86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
6B (n=86, 87)	97.67 (91.85 to 99.72)	100 (95.85 to 100)		
9V (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
14 (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
18C (n=86, 87)	100 (95.8 to 100)	98.85 (93.76 to 99.97)		
19F (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
23F (n=86, 87)	98.84 (93.69 to 99.97)	100 (95.85 to 100)		
1 (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
3 (n=85, 87)	70.59 (59.71 to 79.98)	79.31 (69.29 to 87.25)		

5 (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
6A (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
7F (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		
19A (n=86, 87)	100 (95.8 to 100)	100 (95.85 to 100)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-2.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.15
upper limit	1.96

Statistical analysis title	Serotype 9V

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 14

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 18C

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	1.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.13
upper limit	6.24

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.32
upper limit	3.1

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-8.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.93
upper limit	4.42

Statistical analysis title	Serotype 5
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	4.31

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level >=0.35 mcg/mL 1 Month After Toddler Dose: Group 1A, 1B, 1C

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level >=0.35 mcg/mL 1 Month After Toddler Dose: Group 1A, 1B, 1C

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% CI for the 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) were presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate IgG antibody concentration to the given serotype for each arm, respectively.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	46	21	
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
6B (n=21, 45, 20)	100 (83.89 to 100)	95.56 (84.85 to 99.46)	100 (83.16 to 100)	
9V (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
14 (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
18C (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
19F (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
23F (n=21, 45, 20)	100 (83.89 to 100)	97.78 (88.23 to 99.94)	100 (83.16 to 100)	
1 (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
3 (n=21, 44, 20)	95.24 (76.18 to 99.88)	68.18 (52.42 to 81.39)	50 (27.5 to 72.8)	
5 (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
6A (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	
7F (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	

19A (n=21, 45, 20)	100 (83.89 to 100)	100 (92.13 to 100)	100 (83.16 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Before Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Before Toddler Dose

End point description:

Geometric mean concentration (GMC) 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively.

End point type	Secondary

End point timeframe:

Before Toddler Dose (pre-vaccination)

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n= 85, 85)	0.31 (0.26 to 0.37)	0.41 (0.34 to 0.49)		
6B (n= 82, 85)	0.48 (0.39 to 0.58)	0.94 (0.79 to 1.11)		
9V (n= 85, 85)	0.39 (0.33 to 0.46)	0.62 (0.53 to 0.72)		
14 (n= 85, 85)	2.02 (1.68 to 2.43)	2.36 (1.94 to 2.87)		
18C (n=85, 85)	0.32 (0.28 to 0.37)	0.3 (0.26 to 0.36)		
19F (n=85, 85)	0.68 (0.57 to 0.8)	0.93 (0.79 to 1.1)		
23F (n=81, 83)	0.24 (0.18 to 0.31)	0.4 (0.33 to 0.48)		
1 (n=85, 85)	0.39 (0.34 to 0.46)	0.41 (0.35 to 0.48)		
3 (n=84, 84)	0.07 (0.05 to 0.09)	0.11 (0.09 to 0.14)		
5 (n=82, 85)	0.74 (0.64 to 0.87)	1.06 (0.9 to 1.26)		

6A (n=85, 85)	0.54 (0.45 to 0.65)	1.01 (0.82 to 1.24)		
7F (n=85, 85)	0.72 (0.63 to 0.82)	0.84 (0.73 to 0.96)		
19A (n=85, 85)	0.86 (0.72 to 1.03)	1.57 (1.27 to 1.92)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the ratio difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.97

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.66

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.8

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the ratio difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.12

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the ratio difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	1.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.32

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the ratio difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.92

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	0.83

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t

distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.2

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	0.87

Statistical analysis title	Serotype 5

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	0.88

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	0.7

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.03

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	0.72

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Toddler Dose

End point description:

Geometric mean concentration (GMC) 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively.

End point type	Secondary

End point timeframe:

1 Month After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n= 86, 87)	2.57 (2.18 to 3.03)	3.97 (3.32 to 4.74)		
6B (n=86, 87)	4.42 (3.64 to 5.37)	7.27 (6.09 to 8.68)		
9V (n=86, 87)	2.3 (1.99 to 2.66)	3.06 (2.62 to 3.56)		
14 (n=86, 87)	9.24 (7.66 to 11.14)	11.02 (9.44 to 12.86)		
18C (n=86, 87)	2.37 (2.02 to 2.79)	2.81 (2.32 to 3.4)		
19F (n=86, 87)	7.38 (6.23 to 8.76)	11.67 (9.47 to 14.36)		
23F (n=86, 87)	2.45 (2.01 to 2.98)	4.03 (3.36 to 4.85)		
1 (n=86, 87)	3.32 (2.83 to 3.89)	4.09 (3.42 to 4.89)		

3 (n=85, 87)	0.52 (0.44 to 0.62)	0.57 (0.49 to 0.65)		
5 (n=86, 87)	2.63 (2.28 to 3.02)	3.72 (3.19 to 4.33)		
6A (n=86, 87)	5.64 (4.86 to 6.54)	7.84 (6.59 to 9.33)		
7F (n=86, 87)	4.25 (3.75 to 4.82)	5.13 (4.48 to 5.87)		
19A (n=86, 87)	5.57 (4.66 to 6.65)	8.84 (7.45 to 10.48)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.82

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.79

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.93

Statistical analysis title	Serotype 14
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.07

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.08

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.83

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	0.79

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.03

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.15

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.87

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.9

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.81

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 1 Year After Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 1 Year After Toddler Dose

End point description:

The persistence of the antibody response induced by 13vPnC was described by geometric mean concentration (GMC) 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). GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable Toddler Immunogenicity Population. Here 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure during specified follow-up period and 'n' signifies subjects with a determinate IgG concentration to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

1 Year After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	80		
Units: mcg/mL				
geometric mean (confidence interval 95%)				

4 (n= 80, 79)	0.3 (0.25 to 0.36)	0.37 (0.31 to 0.44)		
6B (n=80, 80)	1.26 (1.02 to 1.57)	2.01 (1.69 to 2.39)		
9V (n=80, 80)	0.61 (0.48 to 0.78)	0.98 (0.82 to 1.19)		
14 (n=79, 80)	1.43 (1.15 to 1.78)	1.73 (1.4 to 2.14)		
18C (n=80, 79)	0.33 (0.27 to 0.41)	0.66 (0.54 to 0.81)		
19F (n=80, 79)	0.96 (0.8 to 1.15)	1.78 (1.4 to 2.26)		
23F (n=79, 80)	0.59 (0.47 to 0.74)	1.24 (1.01 to 1.52)		
1 (n=78, 80)	0.4 (0.35 to 0.46)	0.53 (0.45 to 0.62)		
3 (n=78, 78)	0.13 (0.1 to 0.17)	0.22 (0.16 to 0.3)		
5 (n=79, 78)	1.1 (0.91 to 1.32)	1.63 (1.35 to 1.97)		
6A (n=80, 79)	1.08 (0.89 to 1.32)	1.59 (1.34 to 1.9)		
7F (n=79, 80)	0.68 (0.59 to 0.8)	0.83 (0.72 to 0.96)		
19A (n=80, 80)	1.61 (1.22 to 2.12)	3.16 (2.53 to 3.95)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.04

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm

	Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.83

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
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	Serotype 14
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.12

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	0.67

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.72

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	0.64

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.94

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.9

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.87

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.88

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.02

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.72

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 2 Years After Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 2 Years After Toddler Dose

End point description:

The persistence of the antibody response induced by 13vPnC was described by geometric mean concentration (GMC) 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). GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable Toddler Immunogenicity Population. Here 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure during specified follow-up period and 'n' signifies subjects with a determinate IgG concentration to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

2 Years After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	71		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n=70, 71)	0.19 (0.16 to 0.23)	0.24 (0.2 to 0.29)		
6B (n=70, 70)	1.44 (1.13 to 1.85)	2.7 (2.1 to 3.48)		
9V (n=71, 70)	0.74 (0.58 to 0.94)	0.99 (0.8 to 1.23)		
14 (n=70, 71)	1.06 (0.78 to 1.43)	1.37 (1.03 to 1.82)		
18C (n=69, 71)	0.32 (0.24 to 0.42)	0.57 (0.47 to 0.69)		
19F (n=71, 70)	1.1 (0.83 to 1.46)	2.43 (1.71 to 3.44)		
23F (n=71, 71)	1.03 (0.77 to 1.38)	1.83 (1.42 to 2.37)		
1 (n=70, 69)	0.32 (0.26 to 0.38)	0.39 (0.32 to 0.47)		
3 (n=65, 63)	0.17 (0.12 to 0.25)	0.27 (0.18 to 0.4)		
5 (n=69, 69)	1.34 (1.07 to 1.68)	1.97 (1.6 to 2.41)		
6A (n=71, 71)	1.41 (1.09 to 1.82)	2.1 (1.64 to 2.7)		
7F (n=71, 70)	0.6 (0.5 to 0.71)	0.67 (0.57 to 0.8)		
19A (n=71, 71)	2.33 (1.76 to 3.1)	4.36 (3.4 to 5.61)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.03

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.76

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.03

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t

distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.17

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.78

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	0.71

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.83

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.07

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.11

Statistical analysis title	Serotype 5

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.92

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.95

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.13

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratios of GMCs were calculated by back transforming the mean difference between vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC Ratio
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	0.78

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Infant Series: Group 1A, 1B, 1C

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Infant Series: Group 1A, 1B, 1C

End point description:

Geometric mean concentration (GMC) 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMCs

were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively. Evaluable Infant Immunogenicity Population.

End point type	Secondary

End point timeframe:

1 Month After Infant Series

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	50	25	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n=24, 50, 25)	2.5 (1.92 to 3.24)	1.86 (1.47 to 2.37)	1.73 (1.2 to 2.49)	
6B (n=24, 50, 25)	1.23 (0.74 to 2.07)	0.61 (0.42 to 0.88)	0.62 (0.3 to 1.31)	
9V (n=24, 50, 25)	1.44 (1.02 to 2.03)	1.25 (1.02 to 1.53)	1.14 (0.78 to 1.65)	
14 (n=24, 50, 25)	8.95 (6.44 to 12.42)	7.13 (5.65 to 8.98)	6.95 (4.2 to 11.5)	
18C (n=24, 50, 25)	2.58 (1.97 to 3.37)	1.78 (1.44 to 2.19)	1.72 (1.22 to 2.43)	
19F (n=24, 50, 25)	2.46 (1.77 to 3.43)	2.06 (1.67 to 2.55)	2.28 (1.61 to 3.24)	
23F (n=24, 50, 25)	1.38 (0.84 to 2.27)	0.65 (0.48 to 0.89)	0.95 (0.66 to 1.35)	
1 (n=24, 50, 25)	1.56 (1.12 to 2.18)	1.21 (0.96 to 1.52)	1.1 (0.75 to 1.6)	
3 (n=24, 50, 25)	1.28 (0.86 to 1.9)	0.75 (0.6 to 0.93)	0.67 (0.49 to 0.91)	
5 (n=24, 50, 25)	0.85 (0.57 to 1.28)	0.5 (0.36 to 0.69)	0.46 (0.26 to 0.82)	
6A (n=24, 49, 25)	1.74 (1.19 to 2.55)	1.15 (0.84 to 1.57)	0.98 (0.59 to 1.65)	
7F (n=24, 50, 25)	2.43 (1.56 to 3.77)	1.99 (1.61 to 2.46)	2.18 (1.55 to 3.06)	
19A (n=24, 50, 25)	3.43 (2.52 to 4.67)	2.6 (2.08 to 3.25)	2.88 (2.06 to 4.02)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Before Toddler Dose: Group 1A, 1B, 1C

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Before Toddler Dose: Group 1A, 1B, 1C

End point description:

Geometric mean concentration (GMC) 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively. Evaluable Toddler Immunogenicity Population.

End point type	Secondary

End point timeframe:

Before Toddler Dose (pre-vaccination)

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	46	21	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n= 20, 44, 21)	0.37 (0.27 to 0.5)	0.28 (0.22 to 0.36)	0.32 (0.22 to 0.46)	
6B (n= 20, 42, 20)	0.59 (0.42 to 0.83)	0.42 (0.31 to 0.56)	0.49 (0.3 to 0.8)	
9V (n= 20, 44, 21)	0.43 (0.3 to 0.6)	0.36 (0.28 to 0.46)	0.44 (0.33 to 0.6)	
14 (n=20, 44, 21)	2.48 (1.74 to 3.54)	1.83 (1.4 to 2.38)	2.04 (1.33 to 3.12)	
18C (n=20, 44, 21)	0.35 (0.25 to 0.48)	0.3 (0.24 to 0.36)	0.34 (0.24 to 0.49)	
19F (n=20, 44, 21)	0.96 (0.57 to 1.61)	0.58 (0.48 to 0.71)	0.67 (0.52 to 0.87)	
23F (n=20, 41, 20)	0.31 (0.19 to 0.52)	0.21 (0.14 to 0.32)	0.24 (0.14 to 0.41)	
1 (n=20, 44, 21)	0.37 (0.27 to 0.52)	0.39 (0.32 to 0.48)	0.42 (0.3 to 0.61)	
3 (n=20, 44, 20)	0.13 (0.07 to 0.24)	0.06 (0.04 to 0.08)	0.05 (0.02 to 0.09)	
5 (n=19, 43, 20)	0.75 (0.56 to 1.01)	0.71 (0.55 to 0.9)	0.81 (0.62 to 1.06)	
6A (n=20, 44, 21)	0.66 (0.46 to 0.93)	0.49 (0.38 to 0.63)	0.55 (0.35 to 0.85)	
7F (n=20, 44, 21)	0.71 (0.55 to 0.92)	0.64 (0.54 to 0.77)	0.91 (0.69 to 1.19)	
19A (n=20, 44, 21)	1.2 (0.76 to 1.89)	0.72 (0.57 to 0.91)	0.92 (0.66 to 1.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Toddler Dose: Group 1A, 1B, 1C

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Toddler Dose: Group 1A, 1B, 1C

End point description:

Geometric mean concentration (GMC) 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype for each arm, respectively. Evaluable Toddler Immunogenicity Population.

End point type	Secondary

End point timeframe:

1 Month After Toddler Dose

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	46	21	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n= 21, 45, 20)	3.58 (2.66 to 4.83)	2.87 (2.29 to 3.59)	1.41 (1.05 to 1.88)	
6B (n= 21, 45, 20)	6.28 (4.6 to 8.58)	4.28 (3.18 to 5.75)	3.29 (2.24 to 4.84)	
9V (n= 21, 45, 20)	2.99 (2.26 to 3.96)	2.23 (1.81 to 2.74)	1.88 (1.41 to 2.52)	
14 (n=21, 45, 20)	13.2 (9.65 to 18.05)	8.84 (6.58 to 11.9)	7.01 (5.15 to 9.54)	
18C (n=21, 45, 20)	3.71 (2.77 to 4.97)	2.4 (1.95 to 2.96)	1.45 (1.05 to 2)	
19F (n=21, 45, 20)	10.45 (8.2 to 13.32)	7.39 (5.62 to 9.71)	5.12 (3.91 to 6.72)	
23F (n=21, 45, 20)	3.57 (2.54 to 5.02)	2.41 (1.8 to 3.21)	1.71 (1.12 to 2.62)	
1 (n=21, 45, 20)	4.78 (3.61 to 6.34)	3.31 (2.62 to 4.18)	2.28 (1.74 to 2.99)	
3 (n=21, 44, 20)	0.88 (0.61 to 1.25)	0.51 (0.41 to 0.64)	0.31 (0.23 to 0.43)	
5 (n=21, 45, 20)	3.41 (2.69 to 4.32)	2.66 (2.14 to 3.3)	1.95 (1.54 to 2.47)	
6A (n=21, 45, 20)	6.95 (5.18 to 9.33)	5.81 (4.68 to 7.22)	4.23 (3.22 to 5.56)	
7F (n=21, 45, 20)	5.29 (4.11 to 6.8)	4.09 (3.41 to 4.89)	3.69 (2.84 to 4.8)	
19A (n=21, 45, 20)	8.63 (6.51 to 11.43)	5.28 (3.96 to 7.04)	3.96 (3.17 to 4.96)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 1 Year After Toddler Dose: Group 1A, 1B, 1C

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 1 Year After Toddler Dose: Group 1A, 1B, 1C

End point description:

The persistence of the antibody response induced by 13vPnC was described by geometric mean concentration (GMC) 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). GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable Toddler Immunogenicity Population. Here 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure during specified follow-up period and 'n' signifies subjects with a determinate IgG concentration to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

1 Year After Toddler Dose

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	43	19	
Units: mcg/mL (microgram per milliliter)				
geometric mean (confidence interval 95%)				
4 (n=18, 43, 19)	0.3 (0.19 to 0.46)	0.29 (0.23 to 0.37)	0.32 (0.21 to 0.49)	
6B (n=18, 43, 19)	1.49 (0.84 to 2.66)	1.28 (0.96 to 1.7)	1.06 (0.7 to 1.6)	
9V (n=18, 43, 19)	0.59 (0.37 to 0.93)	0.56 (0.42 to 0.75)	0.8 (0.4 to 1.59)	
14 (n=18, 42, 19)	1.37 (0.86 to 2.19)	1.38 (1.09 to 1.75)	1.62 (0.83 to 3.16)	
18C (n=18, 43, 19)	0.39 (0.26 to 0.57)	0.31 (0.24 to 0.41)	0.32 (0.17 to 0.59)	
19F (n=18, 43, 19)	1.27 (0.81 to 2)	0.89 (0.7 to 1.14)	0.86 (0.62 to 1.21)	
23F (n=18, 42, 19)	0.79 (0.5 to 1.26)	0.54 (0.4 to 0.74)	0.53 (0.3 to 0.91)	
1 (n=18, 41, 19)	0.39 (0.3 to 0.5)	0.38 (0.32 to 0.47)	0.45 (0.31 to 0.64)	
3 (n=18, 41, 19)	0.17 (0.1 to 0.29)	0.12 (0.09 to 0.17)	0.11 (0.05 to 0.23)	
5 (n=18, 42, 19)	0.87 (0.59 to 1.28)	1.24 (0.93 to 1.64)	1.05 (0.77 to 1.44)	
6A (n=18, 43, 19)	1.17 (0.73 to 1.87)	1.05 (0.8 to 1.4)	1.07 (0.72 to 1.59)	
7F (n=18, 42, 19)	0.65 (0.47 to 0.91)	0.65 (0.52 to 0.81)	0.81 (0.61 to 1.08)	
19A (n=18, 43, 19)	2.12 (0.9 to 5.01)	1.5 (1.05 to 2.14)	1.45 (0.95 to 2.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 2 Years After Toddler Dose: Group 1A, 1B, 1C

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Persistence 2 Years After Toddler Dose: Group 1A, 1B, 1C

End point description:

The persistence of the antibody response induced by 13vPnC was described by geometric mean concentration (GMC) 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). GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. GMCs were calculated using all subjects with available data for the specified blood draw. CIs were calculated as back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate IgG concentration to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

2 Years After Toddler Dose

End point values	13vPnC Group 1A	13vPnC Group 1B	13vPnC Group 1C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	17[9]	36[10]	18[11]	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
4 (n=17, 35, 18)	0.17 (0.11 to 0.28)	0.19 (0.16 to 0.24)	0.21 (0.13 to 0.33)	
6B (n=17, 35, 18)	1.39 (0.81 to 2.4)	1.81 (1.28 to 2.56)	0.96 (0.58 to 1.6)	
9V (n=17, 36, 18)	0.68 (0.39 to 1.17)	0.83 (0.59 to 1.16)	0.63 (0.36 to 1.12)	
14 (n=17, 35, 18)	1.27 (0.59 to 2.76)	1.02 (0.71 to 1.48)	0.96 (0.47 to 1.96)	
18C (n=16, 35, 18)	0.34 (0.18 to 0.65)	0.35 (0.23 to 0.52)	0.26 (0.16 to 0.44)	
19F (n=17, 36, 18)	1.53 (0.83 to 2.81)	0.93 (0.68 to 1.28)	1.13 (0.5 to 2.53)	
23F (n=17, 36, 18)	1.14 (0.6 to 2.15)	1.41 (0.95 to 2.09)	0.5 (0.27 to 0.9)	
1 (n=17, 35, 18)	0.32 (0.23 to 0.44)	0.35 (0.26 to 0.47)	0.26 (0.18 to 0.39)	
3 (n=16, 33, 16)	0.2 (0.1 to 0.39)	0.19 (0.11 to 0.3)	0.14 (0.06 to 0.34)	

5 (n=17, 35, 17)	1.18 (0.67 to 2.11)	1.67 (1.25 to 2.25)	0.97 (0.62 to 1.5)	
6A (n=17, 36, 18)	1.32 (0.87 to 1.99)	1.58 (1.1 to 2.26)	1.2 (0.63 to 2.3)	
7F (n=17, 36, 18)	0.61 (0.39 to 0.96)	0.68 (0.54 to 0.84)	0.46 (0.32 to 0.67)	
19A (n=17, 36, 18)	3.04 (1.64 to 5.64)	2.46 (1.69 to 3.58)	1.64 (0.83 to 3.23)	

Notes:

[9] - 'N'(number of subjects analyzed)signifies those subjects who were evaluable for this outcome measure
[10] - 'N'(number of subjects analyzed)signifies those subjects who were evaluable for this outcome measure
[11] - 'N'(number of subjects analyzed)signifies those subjects who were evaluable for this outcome measure

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After Infant Series

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After Infant Series[12]

End point description:

Antibody-mediated serum OPA against the 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) was measured centrally using a pneumococcal OPA assay. Results were expressed as OPA titers. OPA titers were logarithmically transformed for analysis; geometric means calculated and expressed as geometric mean titers (GMTs). Evaluable Infant Immunogenicity Population. Here n' signifies subjects with a determinate OPA titer to the given serotype for each arm respectively.

End point type	Secondary

End point timeframe:

1 Month After Infant Series

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was planned to be reported in subjects of 13vPnC (Group 2) and 13vPnC (G roup 1) groups only.

End point values	13vPnC Group 2 (Term Infant)	13vPnC Group 1 (Preterm Infant)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	98	99		
Units: titer				
geometric mean (confidence interval 95%)				
4 (n=58, 62)	923 (746.9 to 1139.7)	1231 (986.5 to 1537.3)		
6B (n=51, 61)	732 (494 to 1086)	835 (478.6 to 1455.2)		
9V (n=54, 60)	211 (108.2 to 413.4)	151 (70.8 to 321.1)		
14 (n=55, 66)	1033 (735.7 to 1451)	1298 (968.3 to 1740.3)		
18C (n=56, 63)	2057 (1594 to 2655.1)	2931 (2341.2 to 3669.3)		

19F (n= 55, 58)	335 (237.2 to 472.3)	417 (330.7 to 525.8)		
23F (n=55, 60)	582 (413.7 to 817.8)	733 (539.3 to 997.3)		
1 (n=88, 87)	13 (10 to 16.8)	10 (8 to 13.4)		
3 (n=83, 86)	57 (46.3 to 69.5)	61 (51.2 to 73.2)		
5 (n=83, 85)	64 (47.2 to 86.9)	37 (25.9 to 53.9)		
6A (n=88, 88)	1287 (980.1 to 1691.1)	1566 (1312.3 to 1869)		
7F (n=93, 86)	1539 (1297.4 to 1826.3)	1605 (1277.9 to 2014.7)		
19A (n=92, 86)	244 (204.1 to 290.6)	283 (232.4 to 344.1)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.81

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	2.2

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.93

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.98

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the

Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	2

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.89

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.99

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.15

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.41

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.94

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.68

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.39

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.51

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) Before Toddler Dose

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) Before Toddler Dose

End point description:

Antibody-mediated serum OPA against the 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) was measured centrally using a pneumococcal OPA assay. Results were expressed as OPA titers. OPA titers were logarithmically transformed for analysis; geometric means calculated and expressed as geometric mean titers (GMTs). Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate OPA titer to the given serotype for each arm respectively.

End point type	Secondary

End point timeframe:

Before the toddler dose (pre-vaccination)

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: titer				
geometric mean (confidence interval 95%)				
4 (n= 56, 59)	10 (6 to 15.3)	13 (7.9 to 21.9)		
6B (n= 59, 62)	12 (6.8 to 20.1)	15 (8.5 to 25.6)		
9V (n=52, 63)	11 (6.2 to 20.9)	7 (4.9 to 11.1)		

14 (n= 60, 55)	242 (148.5 to 394)	389 (260.4 to 582.2)		
18C (n= 54, 58)	32 (16.1 to 61.7)	51 (26.8 to 98.3)		
19F (n= 57, 60)	6 (4.1 to 7.4)	4 (3.8 to 4.7)		
23F (n=59, 62)	11 (6.9 to 19)	16 (9.6 to 26.6)		
1 (n=76, 80)	6 (4.5 to 6.8)	4 (3.9 to 4.8)		
3 (n=73, 77)	8 (6.2 to 10)	8 (6.6 to 10.4)		
5 (n=74, 79)	5 (4.2 to 6)	5 (4.2 to 5.6)		
6A (n=69, 76)	45 (25.2 to 81.1)	91 (56.6 to 146.3)		
7F (n=75, 79)	228 (137.6 to 377.1)	188 (109.3 to 323.1)		
19A (n=77, 79)	9 (6.3 to 12)	10 (7.1 to 14.8)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.44

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.71

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	3.12

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.17

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the

Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	1.55

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.77

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	1.46

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	1.6

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.33

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.31

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	1.04

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	2.53

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.37

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After Toddler Dose

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After Toddler Dose

End point description:

Antibody-mediated serum OPA against the 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) was measured centrally using a pneumococcal OPA assay. Results were expressed as OPA titers. OPA titers were logarithmically transformed for analysis; geometric means calculated and expressed as geometric mean titers (GMTs). Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate OPA titer to the given serotype for each arm respectively.

End point type	Secondary

End point timeframe:

1 Month After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: titer				
geometric mean (confidence interval 95%)				
4 (n= 67, 61)	1154 (879.2 to 1514.5)	1757 (1329.1 to 2322.4)		
6B (n= 64, 61)	1229 (877.2 to 1722.1)	1406 (1003.4 to 1970.3)		
9V (n=60, 58)	1871 (1217.8 to 2873.6)	2542 (1711.6 to 3775.2)		

14 (n= 62, 62)	1294 (969 to 1728.4)	1651 (1300.1 to 2097.1)		
18C (n= 62, 63)	2464 (1696 to 3579.4)	4510 (3399.7 to 5981.7)		
19F (n= 61, 62)	376 (229.1 to 617.1)	640 (431.5 to 948.3)		
23F (n=65, 63)	1048 (738.6 to 1488)	1657 (1217.7 to 2255)		
1 (n=80, 83)	59 (43.7 to 78.6)	107 (83 to 137)		
3 (n=78, 79)	114 (97.1 to 132.7)	121 (103.4 to 140.4)		
5 (n=80, 83)	166 (127.9 to 216.3)	260 (203.9 to 331.9)		
6A (n=78, 74)	1978 (1571.5 to 2489.7)	3154 (2606 to 3816)		
7F (n=81, 82)	2915 (2453.4 to 3462.7)	3154 (2746.2 to 3622.4)		
19A (n=81, 82)	558 (456.3 to 682.6)	825 (692.4 to 983.8)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	0.97

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.4

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.31

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.14

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	0.87

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	1.1

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	1.01

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.81

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.17

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	0.91

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.85

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.15

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.88

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Year After Toddler Dose

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Year After Toddler Dose

End point description:

Antibody-mediated serum OPA against the 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) was measured centrally using a pneumococcal OPA assay. Results were expressed as OPA titers. OPA titers were logarithmically transformed for analysis; geometric means calculated and expressed as geometric mean titers (GMTs). Evaluable Toddler Immunogenicity Population. 'n' signifies subjects with a determinate OPA titer to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

1 Year After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80[13]	80[14]		
Units: titer				
geometric mean (confidence interval 95%)				
4 (n= 66, 59)	24 (12.9 to 45.5)	29 (15.2 to 54.5)		
6B (n= 65, 59)	38 (19 to 74.9)	36 (19.2 to 68.8)		
9V (n=61, 63)	141 (67.5 to 293.1)	244 (126.3 to 469.7)		
14 (n= 59, 54)	276 (169 to 449.4)	372 (236.1 to 586.5)		
18C (n= 62, 60)	33 (16.4 to 67.4)	121 (56.9 to 258.1)		
19F (n= 67, 57)	11 (6.2 to 17.7)	18 (9.6 to 35.4)		
23F (n=67, 62)	45 (23.7 to 86.6)	168 (92.4 to 303.9)		
1 (n=76, 74)	5 (4.2 to 6.3)	5 (4.3 to 5.8)		
3 (n=76, 70)	11 (8.6 to 15.4)	13 (9.2 to 18.7)		
5 (n=72, 70)	8 (5.6 to 10.4)	10 (7 to 13.3)		
6A (n=70, 70)	98 (53 to 183)	255 (152.9 to 424.8)		
7F (n=71, 71)	599 (411 to 873.3)	533 (348.3 to 814.1)		
19A (n=74, 73)	28 (17.2 to 43.9)	54 (34.2 to 85.5)		

Notes:

[13] - N (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure

[14] - N (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	2.05

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	2.63

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	1.53

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.44

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.76

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	1.3

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	0.65

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.32

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.37

Statistical analysis title	Serotype 5

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.23

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	0.86

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.97

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	0.97

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 2 Years After Toddler Dose

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 2 Years After Toddler Dose

End point description:

Antibody-mediated serum OPA against the 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) was measured using a pneumococcal OPA assay. Results were expressed as OPA titers. OPA titers were logarithmically transformed for analysis; geometric means calculated and expressed as geometric mean titers (GMTs). Evaluable Toddler Immunogenicity Population. Here 'N' (number of

subjects analyzed) signifies those subjects who were evaluable for this outcome measure during specified follow-up period and 'n' signifies subjects with a determinate OPA titer to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

2 Years After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	71		
Units: titer				
geometric mean (confidence interval 95%)				
4 (n= 46, 54)	15 (7 to 32.9)	17 (9 to 32.6)		
6B (n= 56, 48)	29 (13.7 to 59.9)	27 (12.4 to 58.2)		
9V (n=50, 55)	132 (57.5 to 301.5)	75 (34.7 to 163.7)		
14 (n= 49, 45)	262 (142 to 482.8)	296 (161.6 to 543.8)		
18C (n= 56, 56)	14 (7.1 to 25.9)	29 (14.3 to 57.9)		
19F (n= 60, 58)	13 (7.4 to 22.5)	20 (10.1 to 39.9)		
23F (n=58, 59)	60 (29.7 to 122.2)	135 (71.2 to 255.3)		
1 (n=70, 68)	5 (4.1 to 5.4)	4 (3.9 to 4.6)		
3 (n=69, 66)	11 (8.1 to 15.2)	16 (10.7 to 24.2)		
5 (n=68, 69)	5 (4.1 to 5.6)	7 (5.4 to 9.4)		
6A (n=68, 62)	42 (21.5 to 81.1)	102 (53.7 to 193.4)		
7F (n=64, 65)	170 (87.7 to 330.9)	269 (155.6 to 463.7)		
19A (n=68, 67)	22 (13.6 to 37.1)	50 (30.1 to 82.6)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	2.37

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	3.07

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	5.36

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	2.07

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	1.21

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.53

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	1.15

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.31

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.92

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.14

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	1.03

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	0.91

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of GMTs calculated by back transforming the mean difference between the groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.48

Secondary: Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 1 Month After Infant Series

End point title	Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 1 Month After Infant Series[15]

End point description:

Percentage of subjects achieving OPA titer >=LLOQ 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) determined in blood samples of all subjects was presented. Exact 2-sided CI based on observed proportion of subjects. LLOQ for each serotype: 1=18; 3=12; 4=21; 5=29; 6A=37; 6B=43; 7F=210; 9V=345; 14=35; 18C=31; 19A=18; 19F=48; 23F=13. Evaluable Infant Immunogenicity Population. Here 'n' signifies subjects with a determinate OPA antibody titer to the given serotype for each arm respectively.

End point type	Secondary

End point timeframe:

1 Month After Infant Series

Notes:

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

Justification:

This end point was planned to be reported in subjects of 13vPnC (Group 2) and 13vPnC (Group 1) group s only.

End point values	13vPnC Group 2 (Term Infant)	13vPnC Group 1 (Preterm Infant)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	99	98		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n= 58, 62)	100 (93.84 to 100)	100 (94.22 to 100)		
6B (n= 51, 61)	90.2 (78.59 to 96.74)	95.08 (86.29 to 98.97)		
9V (n= 54, 60)	64.81 (50.62 to 77.32)	71.67 (58.56 to 82.55)		
14 (n= 55, 66)	100 (93.51 to 100)	96.97 (89.48 to 99.63)		
18C (n= 56, 63)	100 (93.62 to 100)	100 (94.31 to 100)		
19F (n= 55, 58)	100 (93.51 to 100)	96.55 (88.09 to 99.58)		
23F (n= 55, 60)	98.18 (90.28 to 99.95)	96.67 (88.47 to 99.59)		
1 (n= 88, 87)	40.91 (30.54 to 51.91)	51.72 (40.75 to 62.58)		
3 (n=83, 86)	100 (95.65 to 100)	95.35 (88.52 to 98.72)		
5 (n= 83, 85)	67.47 (56.3 to 77.35)	83.53 (73.91 to 90.69)		
6A (n= 88, 88)	100 (95.89 to 100)	97.73 (92.03 to 99.72)		
7F (n= 93, 86)	97.85 (92.45 to 99.74)	100 (95.8 to 100)		
19A (n= 92, 86)	98.91 (94.09 to 99.97)	100 (95.8 to 100)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.33
upper limit	5.99

Statistical analysis title	Serotype 6B
Statistical analysis description:	
S Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-4.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.87
upper limit	5.39

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-6.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.28
upper limit	10.67

Statistical analysis title	Serotype 14
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	3.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.68
upper limit	10.57

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.57
upper limit	5.88

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	3.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.32
upper limit	11.91

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.73
upper limit	9.94

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-10.82

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.51
upper limit	4.34

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	4.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	11.48

Statistical analysis title	Serotype 5
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-16.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.15
upper limit	-2.6

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	2.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.96
upper limit	7.97

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-2.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.55
upper limit	2.1

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	197
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.96
upper limit	3.18

Secondary: Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) Before Toddler Dose

End point title	Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) Before Toddler Dose

End point description:

Percentage of subjects achieving OPA titer >=LLOQ 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) determined in blood samples of all subjects was presented. Exact 2-sided CI based on observed proportion of subjects. LLOQ for each serotype: 1=18; 3=12; 4=21; 5=29; 6A=37; 6B=43; 7F=210; 9V=345; 14=35; 18C=31; 19A=18; 19F=48; 23F=13. Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate OPA antibody titer to the given serotype for each arm respectively.

End point type	Secondary

End point timeframe:

Before Toddler Dose (pre-vaccination)

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n=56, 59)	21.43 (11.59 to 34.44)	30.51 (19.19 to 43.87)		
6B (n=59, 62)	22.03 (12.29 to 34.73)	27.42 (16.85 to 40.23)		
9V (n=52, 63)	19.23 (9.63 to 32.53)	12.7 (5.65 to 23.5)		
14 (n=60, 55)	86.67 (75.41 to 94.06)	94.55 (84.88 to 98.86)		
18C (n=54, 58)	44.44 (30.92 to 58.6)	55.17 (41.54 to 68.26)		
19F (n=57, 60)	8.77 (2.91 to 19.3)	1.67 (0.04 to 8.94)		
23F (n=59, 62)	23.73 (13.62 to 36.59)	37.1 (25.16 to 50.31)		
1 (n=76, 80)	11.84 (5.56 to 21.29)	3.75 (0.78 to 10.57)		
3 (n=73, 77)	32.88 (22.33 to 44.87)	40.26 (29.23 to 52.06)		
5 (n=74, 79)	8.11 (3.03 to 16.82)	7.59 (2.84 to 15.8)		
6A (n=69, 76)	52.17 (39.8 to 64.35)	72.37 (60.91 to 82.01)		
7F (n=75, 79)	78.67 (67.68 to 87.29)	73.42 (62.28 to 82.73)		
19A (n=77, 79)	25.97 (16.64 to 37.23)	29.11 (19.43 to 40.42)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 1 (Preterm Infant) v 13vPnC Group 2 (Term Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-9.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.11
upper limit	7.49

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-5.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.03
upper limit	10.4

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	6.53

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.16
upper limit	21.16

Statistical analysis title	Serotype 14
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-7.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.28
upper limit	3.35

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-10.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.01
upper limit	8.11

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	7.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.52
upper limit	17.65

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-13.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.57
upper limit	3.31

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	8.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	17.81

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-7.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.86
upper limit	8.29

Statistical analysis title	Serotype 5
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.82
upper limit	10.08

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-20.19

Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.45
upper limit	-3.95

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	5.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	19.06

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-3.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.51
upper limit	11.13

Secondary: Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 1 Month After Toddler Dose

End point title	Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 1 Month After Toddler Dose

End point description:

Percentage of subjects achieving OPA titer >=LLOQ 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) determined in blood samples of all subjects was presented. Exact 2-sided CI based on observed proportion of subjects. LLOQ for each serotype: 1=18; 3=12; 4=21; 5=29; 6A=37; 6B=43; 7F=210; 9V=345; 14=35; 18C=31; 19A=18; 19F=48; 23F=13. Evaluable Toddler Immunogenicity Population. Here 'n' signifies subjects with a determinate OPA titer to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

1 Month After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	88		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n= 67, 61)	100 (94.64 to 100)	100 (94.13 to 100)		
6B (n= 64, 61)	98.44 (91.6 to 99.96)	98.36 (91.2 to 99.96)		
9V (n= 60, 58)	95 (86.08 to 98.96)	96.55 (88.09 to 99.58)		
14 (n= 62, 62)	100 (94.22 to 100)	100 (94.22 to 100)		
18C (n= 62, 63)	98.39 (91.34 to 99.96)	100 (94.31 to 100)		
19F (n= 61, 62)	88.52 (77.78 to 95.26)	95.16 (86.5 to 98.99)		
23F (n= 65, 63)	98.46 (91.72 to 99.96)	98.41 (91.47 to 99.96)		
1 (n= 80, 83)	87.5 (78.21 to 93.84)	93.98 (86.5 to 98.02)		
3 (n=78, 79)	100 (95.38 to 100)	98.73 (93.15 to 99.97)		
5 (n= 80, 83)	96.25 (89.43 to 99.22)	97.59 (91.57 to 99.71)		
6A (n=78, 74)	100 (95.38 to 100)	100 (95.14 to 100)		
7F (n= 81, 82)	100 (95.55 to 100)	100 (95.6 to 100)		
19A (n= 81, 82)	100 (95.55 to 100)	100 (95.6 to 100)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.59
upper limit	5.89

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.81
upper limit	7.37

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.87
upper limit	7.44

Statistical analysis title	Serotype 14
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.94
upper limit	5.94

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.66
upper limit	4.25

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-6.64

Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.93
upper limit	3.56

Statistical analysis title	Serotype 23F

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.74
upper limit	7.04

Statistical analysis title	Serotype 1

Statistical analysis description:

CI Parameter was percent difference between the groups.
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-6.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.37
upper limit	2.75

Statistical analysis title	Serotype 3

Statistical analysis description:

CI Parameter was percent difference between the groups.
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.37
upper limit	6.85

Statistical analysis title	Serotype 5

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.36
upper limit	5.14

Statistical analysis title	Serotype 6A

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.73
upper limit	5.04

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.48
upper limit	4.55

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.48
upper limit	4.55

Secondary: Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 1 Year After Toddler Dose

End point title	Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 1 Year After Toddler Dose

End point description:

Percentage of subjects achieving OPA titer >=LLOQ 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) determined in blood samples of all subjects was presented. Exact 2-sided CI based on observed proportion of subjects. LLOQ for each serotype: 1=18; 3=12; 4=21; 5=29; 6A=37; 6B=43; 7F=210; 9V=345; 14=35; 18C=31; 19A=18; 19F=48; 23F=13. Evaluable Toddler Immunogenicity Population. Here ‘N’ (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure during specified follow-up period and 'n' signifies subjects with

a determinate OPA titer to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

1 Year After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	80		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n= 66, 59)	34.8 (23.5 to 47.6)	42.4 (29.6 to 55.9)		
6B (n= 65, 59)	41.5 (29.4 to 54.4)	47.5 (34.3 to 60.9)		
9V (n= 61, 63)	62.3 (49 to 74.4)	73 (60.3 to 83.4)		
14 (n= 59, 54)	86.4 (75 to 94)	90.7 (79.7 to 96.9)		
18C (n= 62, 60)	38.7 (26.6 to 51.9)	61.7 (48.2 to 73.9)		
19F (n= 67, 57)	17.9 (9.6 to 29.2)	29.8 (18.4 to 43.4)		
23F (n= 67, 62)	49.3 (36.8 to 61.8)	77.4 (65 to 87.1)		
1 (n= 76, 74)	10.5 (4.7 to 19.7)	10.8 (4.8 to 20.2)		
3 (n=76, 70)	47.4 (35.8 to 59.2)	48.6 (36.4 to 60.8)		
5 (n= 72, 70)	20.8 (12.2 to 32)	31.4 (20.9 to 43.6)		
6A (n=70, 70)	62.9 (50.5 to 74.1)	81.4 (70.3 to 89.7)		
7F (n= 71, 71)	93 (84.3 to 97.7)	90.1 (80.7 to 95.9)		
19A (n= 74, 73)	54.1 (42.1 to 65.7)	72.6 (60.9 to 82.4)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-7.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.5
upper limit	9.9

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.6
upper limit	11.8

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.6
upper limit	6

Statistical analysis title	Serotype 14
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17
upper limit	8.4

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40
upper limit	-4.9

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-11.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.4
upper limit	3.4

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-28.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.9
upper limit	-11

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.9
upper limit	10.3

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.5
upper limit	15.1

Statistical analysis title	Serotype 5
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-10.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.3
upper limit	4.5

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-18.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.3
upper limit	-3

Statistical analysis title	Serotype 7F

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	13.1

Statistical analysis title	Serotype 19A

Statistical analysis description:

Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.

Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.7
upper limit	-2.8

Secondary: Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 2 Years After Toddler Dose

End point title	Percentage of Subjects With OPA Titer >= Lower Limit of Quantitation (LLOQ) 2 Years After Toddler Dose

End point description:

Percentage of subjects achieving OPA titer >=LLOQ 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) determined in blood samples of all subjects was presented. Exact 2-sided CI based on observed proportion of subjects. LLOQ for each serotype: 1=18; 3=12; 4=21; 5=29; 6A=37; 6B=43; 7F=210; 9V=345; 14=35; 18C=31; 19A=18; 19F=48; 23F=13. Evaluable Toddler Immunogenicity Population. Here ‘N’ (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure during specified follow-up period and 'n' signifies subjects with a determinate OPA titer to the given serotype during specified follow-up period for each arm, respectively.

End point type	Secondary

End point timeframe:

2 Years After Toddler Dose

End point values	13vPnC Group 1 (Preterm Infant)	13vPnC Group 2 (Term Infant)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	71		
Units: percentage of subjects				
number (confidence interval 95%)				
4 (n= 46, 54)	21.7 (10.9 to 36.4)	29.6 (18 to 43.6)		
6B (n= 56, 48)	35.7 (23.4 to 49.6)	35.4 (22.2 to 50.5)		
9V (n= 50, 55)	60 (45.2 to 73.6)	52.7 (38.8 to 66.3)		
14 (n= 49, 45)	81.6 (68 to 91.2)	84.4 (70.5 to 93.5)		
18C (n= 56, 56)	21.4 (11.6 to 34.4)	39.3 (26.5 to 53.2)		
19F (n= 60, 58)	25 (14.7 to 37.9)	29.3 (18.1 to 42.7)		
23F (n= 58, 59)	53.4 (39.9 to 66.7)	74.6 (61.6 to 85)		
1 (n= 70, 68)	8.6 (3.2 to 17.7)	2.9 (0.4 to 10.2)		
3 (n=69, 66)	46.4 (34.3 to 58.8)	51.5 (38.9 to 64)		
5 (n= 68, 69)	7.4 (2.4 to 16.3)	21.7 (12.7 to 33.3)		
6A (n=68, 62)	44.1 (32.1 to 56.7)	64.5 (51.3 to 76.3)		
7F (n= 64, 65)	68.8 (55.9 to 79.8)	80 (68.2 to 88.9)		
19A (n= 68, 67)	45.6 (33.5 to 58.1)	67.2 (54.6 to 78.2)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description: Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-7.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.2
upper limit	9.9

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.5
upper limit	19

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	26.2

Statistical analysis title	Serotype 14
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.1
upper limit	13.3

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-17.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.6
upper limit	-0.3

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.6
upper limit	12.1

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.8
upper limit	-3.2

Statistical analysis title	Serotype 1
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	15.2

Statistical analysis title	Serotype 3
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-5.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-22
upper limit	12

Statistical analysis title	Serotype 5
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-14.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.7
upper limit	-2.4

Statistical analysis title	Serotype 6A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-20.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.8
upper limit	-3

Statistical analysis title	Serotype 7F
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-11.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.4
upper limit	4.1

Statistical analysis title	Serotype 19A
Statistical analysis description:	
Exact 2-sided, 95% CI was computed based on the procedure of Chan and Zhang using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC Group 2 (Term Infant) v 13vPnC Group 1 (Preterm Infant)
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percent Difference
Point estimate	-21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.7
upper limit	-4.6

Adverse events information

Timeframe for reporting adverse events:

AEs/SAEs: recorded from 13vPnC infant dose 1 to 2-year follow-up after toddler dose. Subjects recorded pre-specified AEs in electronic diary: local reactions; systemic events (up to 7 days after each vaccine dose)

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included AEs collected in electronic diary (local,systemic reactions for 13vPnC; systematic assessment) and AEs collected on case report form at each visit (nonsystematic assessment). Subjects who received specified dose and had safety data available were evaluable for safety.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	MedDRA

Reporting groups

Reporting group title	13vPnC Group 1 (Preterm Infant) - Infant Series

Reporting group description:

Preterm infant subjects (GA <37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3 and 4 months of age (infant series), assessed from Infant Dose 1 through the blood draw 1 month after Infant Dose 3.

Reporting group title	13vPnC Group 2 (Term Infant) - Infant Series

Reporting group description:

Term infant subjects (GA >=37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series), assessed from Infant Dose 1 through the blood draw 1 month after Infant Dose 3.

Reporting group title	13vPnC Group 1 (Preterm Infant) - After Infant Series

Reporting group description:

Preterm infant subjects (GA <37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3 and 4 months of age (infant series), assessed from blood draw 1 month after infant Dose 3 to before toddler dose.

Reporting group title	13vPnC Group 2 (Term Infant) - After Infant Series

Reporting group description:

Term infant subjects (GA >=37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series), assessed from blood draw 1 month after infant Dose 3 to before toddler dose.

Reporting group title	13vPnC Group 1 (Preterm Infant) - Toddler Dose

Reporting group description:

Preterm infant subjects (GA <37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and 12 months of age (toddler dose), assessed from the toddler dose through the blood draw 1 month after toddler dose.

Reporting group title	13vPnC Group 2 (Term Infant) - Toddler Dose

Reporting group description:

Term infant subjects (GA >=37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and 12 months of age (toddler dose), assessed from the toddler dose through the blood draw 1 month after toddler dose.

Reporting group title	13vPnC Group 1 (Preterm Infant) - 1 Year Follow-up

Reporting group description:

Preterm infant subjects (GA <37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and 12 months of age (toddler dose), assessed from blood draw 1 month after the toddler dose to 1-year follow-up.

Reporting group title	13vPnC Group 2 (Term Infant) - 1 Year Follow-up

Reporting group description:

Term infant subjects (GA >=37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and 12 months of age (toddler dose), assessed from blood draw 1

month after the toddler dose to 1-year follow-up.

Reporting group title	13vPnC Group 1 (Preterm Infant) - 2 Year Follow-up

Reporting group description:

Preterm infant subjects (GA <37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and 12 months of age (toddler dose), assessed from 1-year follow-up after toddler dose to 2-year follow-up after toddler dose.

Reporting group title	13vPnC Group 2 (Term Infant) - 2 Year Follow-up

Reporting group description:

Term infant subjects (GA >=37 weeks) who received single 0.5 mL dose of 13vPnC intramuscularly at 2, 3, 4 months of age (infant series) and 12 months of age (toddler dose), assessed from 1-year follow-up after toddler dose to 2-year follow-up after toddler dose.

Serious adverse events	13vPnC Group 1 (Preterm Infant) - Infant Series	13vPnC Group 2 (Term Infant) - Infant Series	13vPnC Group 1 (Preterm Infant) - After Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 100 (14.00%)	5 / 100 (5.00%)	8 / 100 (8.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Head injury			
alternative dictionary used: MedDRA MedDRA(U)			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hip dysplasia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral palsy			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
CSF shunt operation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
alternative dictionary used: MedDRA MedDRA (U			

subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst torsion			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Autism spectrum disorder			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis reactive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenoviral upper respiratory infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 100 (4.00%)	2 / 100 (2.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	2 / 100 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	1 / 100 (1.00%)	3 / 100 (3.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
alternative assessment type: Systematic			

subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia mycoplasmal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Group 2 (Term Infant) - After Infant Series	13vPnC Group 1 (Preterm Infant) - Toddler Dose	13vPnC Group 2 (Term Infant) - Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 100 (9.00%)	2 / 99 (2.02%)	1 / 97 (1.03%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Head injury			
alternative dictionary used: MedDRA MedDRA(U)			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hip dysplasia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral palsy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
CSF shunt operation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 97 (1.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst torsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Autism spectrum disorder			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis reactive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Adenoviral upper respiratory infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 100 (3.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 infection			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Group 1 (Preterm Infant) - 1 Year Follow-up	13vPnC Group 2 (Term Infant) - 1 Year Follow-up	13vPnC Group 1 (Preterm Infant) - 2 Year Follow-up

Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 99 (13.13%)	8 / 97 (8.25%)	6 / 88 (6.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Head injury			
alternative dictionary used: MedDRA MedDRA(U)			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hip dysplasia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral palsy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	2 / 88 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
CSF shunt operation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	2 / 97 (2.06%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst torsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Autism spectrum disorder			
alternative dictionary used: MedDRA MedDRA (U			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis reactive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenoviral upper respiratory infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 99 (2.02%)	0 / 97 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Systematic			

subjects affected / exposed	4 / 99 (4.04%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human herpesvirus 6 infection			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 99 (2.02%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	1 / 97 (1.03%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Group 2 (Term Infant) - 2 Year Follow-up		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 88 (9.09%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Head injury			
alternative dictionary used: MedDRA MedDRA(U)			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Hip dysplasia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral palsy			
alternative assessment type:			

Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
CSF shunt operation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depressed level of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
alternative dictionary used: MedDRA MedDRA (U			

subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia, obstructive				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intussusception				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Ovarian cyst torsion				
alternative assessment type: Systematic				

subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Autism spectrum disorder			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthritis reactive			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Adenoviral upper respiratory infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			

alternative assessment type: Systematic				
subjects affected / exposed	1 / 88 (1.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative assessment type: Systematic				
subjects affected / exposed	2 / 88 (2.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
alternative assessment type: Systematic				

subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
alternative assessment type: Systematic				
subjects affected / exposed	1 / 88 (1.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Human herpesvirus 6 infection				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral rash				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pneumonia mycoplasmal				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis viral				
alternative assessment type: Systematic				
subjects affected / exposed	1 / 88 (1.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
alternative assessment type: Systematic				
subjects affected / exposed	1 / 88 (1.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis viral				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media acute				
alternative assessment type: Systematic				

subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	13vPnC Group 1 (Preterm Infant) - Infant Series	13vPnC Group 2 (Term Infant) - Infant Series	13vPnC Group 1 (Preterm Infant) - After Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	93 / 100 (93.00%)	90 / 100 (90.00%)	13 / 100 (13.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Injection site erythema			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 100 (5.00%)	3 / 100 (3.00%)	0 / 100 (0.00%)
occurrences (all)	6	3	0
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	4 / 100 (4.00%)	1 / 100 (1.00%)
occurrences (all)	2	4	1
Developmental delay			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Fever ≥38 degree centigrade (°C) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	10 / 86 (11.63%)	12 / 88 (13.64%)	0 / 100 (0.00%)
occurrences (all)	10	12	0
Fever ≥38°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events Systemic			
alternative assessment type: Systematic			
subjects affected / exposed[2]	22 / 79 (27.85%)	25 / 79 (31.65%)	0 / 100 (0.00%)
occurrences (all)	22	25	0
Fever ≥38°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[3]	22 / 79 (27.85%)	25 / 81 (30.86%)	0 / 100 (0.00%)
occurrences (all)	22	25	0
Fever ≥38°C but ≤39°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	9 / 86 (10.47%)	12 / 88 (13.64%)	0 / 100 (0.00%)
occurrences (all)	9	12	0
Fever ≥38°C but ≤39°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	22 / 79 (27.85%)	24 / 79 (30.38%)	0 / 100 (0.00%)
occurrences (all)	22	24	0
Fever ≥38°C but ≤39°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	21 / 78 (26.92%)	25 / 81 (30.86%)	0 / 100 (0.00%)
occurrences (all)	21	25	0
Fever >39°C but ≤40°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	1 / 86 (1.16%)	0 / 85 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Fever >39°C but ≤40°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 73 (0.00%)	1 / 76 (1.32%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Fever >39°C but ≤40°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[9]	1 / 75 (1.33%)	2 / 78 (2.56%)	0 / 100 (0.00%)
occurrences (all)	1	2	0
Fever >40°C Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 86 (0.00%)	0 / 85 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	56 / 92 (60.87%)	37 / 89 (41.57%)	0 / 100 (0.00%)
occurrences (all)	56	37	0
Decreased Appetite (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	55 / 89 (61.80%)	39 / 84 (46.43%)	0 / 100 (0.00%)
occurrences (all)	55	39	0
Decreased Appetite (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	40 / 82 (48.78%)	40 / 84 (47.62%)	0 / 100 (0.00%)
occurrences (all)	40	40	0
Decreased Appetite (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	50 / 91 (54.95%)	31 / 88 (35.23%)	0 / 100 (0.00%)
occurrences (all)	50	31	0
Decreased Appetite (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[15]	49 / 88 (55.68%)	35 / 84 (41.67%)	0 / 100 (0.00%)
occurrences (all)	49	35	0
Decreased Appetite (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	30 / 82 (36.59%)	39 / 84 (46.43%)	0 / 100 (0.00%)
occurrences (all)	30	39	0
Decreased Appetite (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	18 / 88 (20.45%)	15 / 87 (17.24%)	0 / 100 (0.00%)
occurrences (all)	18	15	0
Decreased Appetite (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	20 / 79 (25.32%)	15 / 78 (19.23%)	0 / 100 (0.00%)
occurrences (all)	20	15	0
Decreased Appetite (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	13 / 74 (17.57%)	13 / 79 (16.46%)	0 / 100 (0.00%)
occurrences (all)	13	13	0
Decreased Appetite (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	1 / 86 (1.16%)	0 / 85 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Decreased Appetite (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type:			

Systematic			
subjects affected / exposed[21]	1 / 73 (1.37%)	0 / 76 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Decreased Appetite (Severe) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	1 / 74 (1.35%)	1 / 77 (1.30%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Increased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events Systemic			
alternative assessment type: Systematic			
subjects affected / exposed[23]	65 / 96 (67.71%)	66 / 95 (69.47%)	0 / 100 (0.00%)
occurrences (all)	65	66	0
Increased Sleep (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	63 / 85 (74.12%)	57 / 89 (64.04%)	0 / 100 (0.00%)
occurrences (all)	63	57	0
Increased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	46 / 88 (52.27%)	51 / 88 (57.95%)	0 / 100 (0.00%)
occurrences (all)	46	51	0
Increased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	58 / 96 (60.42%)	57 / 93 (61.29%)	0 / 100 (0.00%)
occurrences (all)	58	57	0
Increased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[27]	58 / 83 (69.88%)	52 / 88 (59.09%)	0 / 100 (0.00%)
occurrences (all)	58	52	0
Increased Sleep (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	43 / 88 (48.86%)	45 / 87 (51.72%)	0 / 100 (0.00%)
occurrences (all)	43	45	0
Increased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	26 / 87 (29.89%)	27 / 88 (30.68%)	0 / 100 (0.00%)
occurrences (all)	26	27	0
Increased Sleep (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	27 / 78 (34.62%)	23 / 78 (29.49%)	0 / 100 (0.00%)
occurrences (all)	27	23	0
Increased Sleep (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	13 / 77 (16.88%)	16 / 80 (20.00%)	0 / 100 (0.00%)
occurrences (all)	13	16	0
Increased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	2 / 86 (2.33%)	2 / 85 (2.35%)	0 / 100 (0.00%)
occurrences (all)	2	2	0
Increased Sleep (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[33]	2 / 73 (2.74%)	1 / 76 (1.32%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Increased Sleep (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	1 / 73 (1.37%)	1 / 77 (1.30%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Irritability or Decreased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	80 / 95 (84.21%)	80 / 97 (82.47%)	0 / 100 (0.00%)
occurrences (all)	80	80	0
Irritability or Decreased Sleep (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	85 / 95 (89.47%)	74 / 95 (77.89%)	0 / 100 (0.00%)
occurrences (all)	85	74	0
Irritability or Decreased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	73 / 92 (79.35%)	77 / 95 (81.05%)	0 / 100 (0.00%)
occurrences (all)	73	77	0
Irritability or Decreased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	72 / 93 (77.42%)	66 / 95 (69.47%)	0 / 99 (0.00%)
occurrences (all)	72	66	0
Irritability or Decreased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[39]	73 / 90 (81.11%)	66 / 92 (71.74%)	0 / 100 (0.00%)
occurrences (all)	73	66	0
Irritability or Decreased Sleep (Mild) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	65 / 90 (72.22%)	68 / 91 (74.73%)	0 / 100 (0.00%)
occurrences (all)	65	68	0
Irritability or Decreased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	40 / 92 (43.48%)	43 / 91 (47.25%)	0 / 100 (0.00%)
occurrences (all)	40	43	0
Irritability or Decreased Sleep (Moderate) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	55 / 85 (64.71%)	38 / 86 (44.19%)	0 / 100 (0.00%)
occurrences (all)	55	38	0
Irritability or Decreased Sleep (Moderate) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	27 / 80 (33.75%)	31 / 87 (35.63%)	0 / 100 (0.00%)
occurrences (all)	27	31	0
Irritability or Decreased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	7 / 86 (8.14%)	5 / 85 (5.88%)	0 / 100 (0.00%)
occurrences (all)	7	5	0
Irritability or Decreased Sleep (Severe) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[45] occurrences (all)	13 / 74 (17.57%) 13	2 / 76 (2.63%) 2	0 / 100 (0.00%) 0
Irritability or Decreased Sleep (Severe) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[46] occurrences (all)	5 / 74 (6.76%) 5	5 / 78 (6.41%) 5	0 / 100 (0.00%) 0
Immune system disorders			
Food allergy alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	2 / 100 (2.00%) 2	0 / 100 (0.00%) 0
Milk allergy alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 100 (0.00%) 0
Allergy to arthropod sting alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory disease alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 100 (0.00%) 0
Investigations			
Cardiac murmur alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 100 (0.00%) 0
Congenital, familial and genetic disorders			

Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Hydrocele			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Beckwith-Wiedemann syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Hypersomnia			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 100 (3.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	3	0	0
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Subdural hygroma			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Eye discharge			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Aphthous stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Constipation			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	3 / 100 (3.00%)	1 / 100 (1.00%)
occurrences (all)	0	3	1
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			

alternative assessment type: Systematic			
subjects affected / exposed	3 / 100 (3.00%)	1 / 100 (1.00%)	1 / 100 (1.00%)
occurrences (all)	3	1	1
Infantile colic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Umbilical hernia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Teething			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	2 / 100 (2.00%)	0 / 100 (0.00%)
occurrences (all)	1	2	0
Dermatitis diaper			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dry skin			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Erythema			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Tenderness (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[47]	46 / 94 (48.94%)	37 / 88 (42.05%)	0 / 100 (0.00%)
occurrences (all)	46	37	0
Tenderness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[48]	41 / 85 (48.24%)	34 / 88 (38.64%)	0 / 100 (0.00%)
occurrences (all)	41	34	0
Tenderness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[49]	32 / 82 (39.02%)	24 / 84 (28.57%)	0 / 100 (0.00%)
occurrences (all)	32	24	0
Tenderness (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[50]	43 / 93 (46.24%)	28 / 88 (31.82%)	0 / 100 (0.00%)
occurrences (all)	43	28	0
Tenderness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[51]	37 / 85 (43.53%)	26 / 84 (30.95%)	0 / 100 (0.00%)
occurrences (all)	37	26	0
Tenderness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[52]	29 / 81 (35.80%)	22 / 84 (26.19%)	0 / 100 (0.00%)
occurrences (all)	29	22	0
Tenderness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[53]	16 / 90 (17.78%)	14 / 85 (16.47%)	0 / 100 (0.00%)
occurrences (all)	16	14	0
Tenderness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[54]	11 / 77 (14.29%)	13 / 83 (15.66%)	0 / 100 (0.00%)
occurrences (all)	11	13	0
Tenderness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[55]	7 / 75 (9.33%)	4 / 78 (5.13%)	0 / 100 (0.00%)
occurrences (all)	7	4	0
Tenderness (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[56]	0 / 86 (0.00%)	0 / 85 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Tenderness (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[57]	0 / 73 (0.00%)	1 / 77 (1.30%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Swelling (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[58]	37 / 94 (39.36%)	26 / 89 (29.21%)	0 / 100 (0.00%)
occurrences (all)	37	26	0
Swelling (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[59]	30 / 84 (35.71%)	35 / 82 (42.68%)	0 / 100 (0.00%)
occurrences (all)	30	35	0
Swelling (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[60]	25 / 83 (30.12%)	35 / 85 (41.18%)	0 / 100 (0.00%)
occurrences (all)	25	35	0
Swelling (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[61]	34 / 91 (37.36%)	25 / 89 (28.09%)	0 / 100 (0.00%)
occurrences (all)	34	25	0
Swelling (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[62]	28 / 83 (33.73%)	35 / 82 (42.68%)	0 / 100 (0.00%)
occurrences (all)	28	35	0
Swelling (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[63]	22 / 82 (26.83%)	35 / 85 (41.18%)	0 / 100 (0.00%)
occurrences (all)	22	35	0
Swelling (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[64]	8 / 91 (8.79%)	7 / 85 (8.24%)	0 / 100 (0.00%)
occurrences (all)	8	7	0
Swelling (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea			
alternative assessment type: Systematic			
subjects affected / exposed[65]	6 / 75 (8.00%)	2 / 76 (2.63%)	0 / 100 (0.00%)
occurrences (all)	6	2	0
Swelling (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea			
alternative assessment type: Systematic			
subjects affected / exposed[66]	4 / 75 (5.33%)	4 / 79 (5.06%)	0 / 100 (0.00%)
occurrences (all)	4	4	0
Swelling (Severe) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[67]	0 / 86 (0.00%)	0 / 85 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Redness (Any) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[68]	31 / 92 (33.70%)	26 / 87 (29.89%)	0 / 100 (0.00%)
occurrences (all)	31	26	0
Redness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[69]	23 / 82 (28.05%)	33 / 82 (40.24%)	0 / 100 (0.00%)
occurrences (all)	23	33	0
Redness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[70]	27 / 82 (32.93%)	40 / 87 (45.98%)	0 / 100 (0.00%)
occurrences (all)	27	40	0
Redness (Mild) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[71]	29 / 90 (32.22%)	25 / 87 (28.74%)	0 / 100 (0.00%)
occurrences (all)	29	25	0
Redness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[72]	23 / 82 (28.05%)	31 / 82 (37.80%)	0 / 100 (0.00%)
occurrences (all)	23	31	0
Redness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[73]	27 / 82 (32.93%)	40 / 87 (45.98%)	0 / 100 (0.00%)
occurrences (all)	27	40	0
Redness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[74]	3 / 88 (3.41%)	4 / 85 (4.71%)	0 / 100 (0.00%)
occurrences (all)	3	4	0
Redness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[75]	2 / 73 (2.74%)	2 / 76 (2.63%)	0 / 100 (0.00%)
occurrences (all)	2	2	0
Redness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[76]	1 / 74 (1.35%)	3 / 79 (3.80%)	0 / 100 (0.00%)
occurrences (all)	1	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute sinusitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 100 (7.00%)	6 / 100 (6.00%)	0 / 100 (0.00%)
occurrences (all)	7	8	0
Bronchitis			
alternative assessment type:			

Systematic			
subjects affected / exposed	5 / 100 (5.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	6	1	0
Ear infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	6 / 100 (6.00%)	1 / 100 (1.00%)
occurrences (all)	0	6	1
Influenza			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 100 (6.00%)	5 / 100 (5.00%)	0 / 100 (0.00%)
occurrences (all)	6	6	0
Oral candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Otitis media			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Otitis media acute			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	1 / 100 (1.00%)
occurrences (all)	1	1	1
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 100 (8.00%)	9 / 100 (9.00%)	4 / 100 (4.00%)
occurrences (all)	9	11	4
Respiratory tract infection bacterial			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection viral			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 100 (5.00%)	4 / 100 (4.00%)	2 / 100 (2.00%)
occurrences (all)	5	4	2
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 100 (8.00%)	10 / 100 (10.00%)	1 / 100 (1.00%)
occurrences (all)	9	13	1

Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	1 / 100 (1.00%)
occurrences (all)	1	1	1
Viral infection			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Viral upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	3	0	0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Herpangina			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 100 (3.00%)	2 / 100 (2.00%)	0 / 100 (0.00%)
occurrences (all)	3	2	0

Non-serious adverse events	13vPnC Group 2 (Term Infant) - After	13vPnC Group 1 (Preterm Infant) -	13vPnC Group 2 (Term Infant) -

	Infant Series	Toddler Dose	Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 100 (11.00%)	84 / 99 (84.85%)	82 / 97 (84.54%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site erythema			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	1 / 97 (1.03%)
occurrences (all)	0	1	1
Developmental delay			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever ≥38 degree centigrade (°C) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 100 (0.00%)	23 / 80 (28.75%)	34 / 78 (43.59%)
occurrences (all)	0	23	34

Fever ≥38°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events Systemic alternative assessment type: Systematic subjects affected / exposed[2]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[3]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[4]	0 / 100 (0.00%)	22 / 80 (27.50%)	33 / 77 (42.86%)
occurrences (all)	0	22	33
Fever ≥38°C but ≤39°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[5]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[6]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[7]	0 / 100 (0.00%)	1 / 74 (1.35%)	3 / 71 (4.23%)
occurrences (all)	0	1	3
Fever >39°C but ≤40°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 100 (0.00%)	0 / 74 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Decreased Appetite (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 100 (0.00%)	50 / 87 (57.47%)	52 / 86 (60.47%)
occurrences (all)	0	50	52
Decreased Appetite (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[13]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 100 (0.00%)	43 / 86 (50.00%)	47 / 84 (55.95%)
occurrences (all)	0	43	47
Decreased Appetite (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 100 (0.00%)	20 / 78 (25.64%)	17 / 73 (23.29%)
occurrences (all)	0	20	17
Decreased Appetite (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type:			

Systematic			
subjects affected / exposed[19]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 100 (0.00%)	1 / 75 (1.33%)	1 / 69 (1.45%)
occurrences (all)	0	1	1
Decreased Appetite (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Severe) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events Systemic			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 100 (0.00%)	48 / 83 (57.83%)	56 / 86 (65.12%)
occurrences (all)	0	48	56
Increased Sleep (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 100 (0.00%)	44 / 82 (53.66%)	50 / 84 (59.52%)
occurrences (all)	0	44	50
Increased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 100 (0.00%)	14 / 76 (18.42%)	18 / 74 (24.32%)
occurrences (all)	0	14	18
Increased Sleep (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 99 (0.00%)	0 / 74 (0.00%)	2 / 70 (2.86%)
occurrences (all)	0	0	2
Increased Sleep (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 100 (0.00%)	76 / 90 (84.44%)	73 / 91 (80.22%)
occurrences (all)	0	76	73
Irritability or Decreased Sleep (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 99 (0.00%)	67 / 90 (74.44%)	68 / 89 (76.40%)
occurrences (all)	0	67	68
Irritability or Decreased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Mild) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 100 (0.00%)	35 / 78 (44.87%)	36 / 80 (45.00%)
occurrences (all)	0	35	36
Irritability or Decreased Sleep (Moderate) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Moderate) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 100 (0.00%)	5 / 76 (6.58%)	3 / 69 (4.35%)
occurrences (all)	0	5	3
Irritability or Decreased Sleep (Severe) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Severe) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Allergy to arthropod sting			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	1	0	0

Respiratory, thoracic and mediastinal disorders			
Allergic respiratory disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Beckwith-Wiedemann syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypersomnia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Subdural hygroma			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	1	0	0
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Constipation			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	2 / 99 (2.02%)	2 / 97 (2.06%)
occurrences (all)	1	2	2
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Teething			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	2 / 97 (2.06%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Cholelithiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	2	0	0
Dermatitis diaper			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dry skin			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Erythema			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[47]	0 / 100 (0.00%)	60 / 86 (69.77%)	47 / 85 (55.29%)
occurrences (all)	0	60	47
Tenderness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[48]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[49]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[50]	0 / 100 (0.00%)	57 / 86 (66.28%)	44 / 85 (51.76%)
occurrences (all)	0	57	44
Tenderness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[51]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[52]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[53]	0 / 100 (0.00%)	16 / 77 (20.78%)	8 / 70 (11.43%)
occurrences (all)	0	16	8
Tenderness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[54]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[55]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tenderness (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[56]	0 / 100 (0.00%)	2 / 74 (2.70%)	0 / 69 (0.00%)
occurrences (all)	0	2	0
Tenderness (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[57]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[58]	0 / 100 (0.00%)	35 / 81 (43.21%)	28 / 80 (35.00%)
occurrences (all)	0	35	28
Swelling (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[59]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[60]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[61]	0 / 100 (0.00%)	31 / 80 (38.75%)	26 / 79 (32.91%)
occurrences (all)	0	31	26
Swelling (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[62]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[63]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[64]	0 / 100 (0.00%)	10 / 76 (13.16%)	7 / 74 (9.46%)
occurrences (all)	0	10	7
Swelling (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea			
alternative assessment type: Systematic			

subjects affected / exposed[65]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea			
alternative assessment type: Systematic			
subjects affected / exposed[66]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling (Severe) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[67]	0 / 100 (0.00%)	1 / 74 (1.35%)	0 / 69 (0.00%)
occurrences (all)	0	1	0
Redness (Any) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[68]	0 / 100 (0.00%)	44 / 85 (51.76%)	41 / 83 (49.40%)
occurrences (all)	0	44	41
Redness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[69]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Redness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[70]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[71]	0 / 100 (0.00%)	44 / 85 (51.76%)	40 / 83 (48.19%)
occurrences (all)	0	44	40
Redness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[72]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[73]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[74]	0 / 100 (0.00%)	5 / 75 (6.67%)	8 / 75 (10.67%)
occurrences (all)	0	5	8
Redness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[75]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[76]	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences (all)	1	1	0
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 100 (3.00%)	3 / 99 (3.03%)	2 / 97 (2.06%)
occurrences (all)	3	3	2
Ear infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	2 / 99 (2.02%)	2 / 97 (2.06%)
occurrences (all)	0	2	2
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	3 / 99 (3.03%)	2 / 97 (2.06%)
occurrences (all)	0	3	2
Influenza			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 100 (2.00%)	6 / 99 (6.06%)	4 / 97 (4.12%)
occurrences (all)	2	6	4
Oral candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	2 / 97 (2.06%)
occurrences (all)	0	0	2
Otitis media acute			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	2 / 97 (2.06%)
occurrences (all)	0	1	2
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	3 / 99 (3.03%)	1 / 97 (1.03%)
occurrences (all)	1	3	1
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	3 / 99 (3.03%)	1 / 97 (1.03%)
occurrences (all)	0	3	1
Respiratory tract infection bacterial			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	5 / 99 (5.05%)	4 / 97 (4.12%)
occurrences (all)	0	5	4
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Viral infection			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Herpangina			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	2 / 97 (2.06%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC Group 1 (Preterm Infant) - 1 Year Follow-up	13vPnC Group 2 (Term Infant) - 1 Year Follow-up	13vPnC Group 1 (Preterm Infant) - 2 Year Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 99 (2.02%)	0 / 97 (0.00%)	1 / 88 (1.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site erythema			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
alternative assessment type:			

Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Developmental delay			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Fever ≥38 degree centigrade (°C) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events Systemic			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[5]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[11]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type:			

Systematic			
subjects affected / exposed[17]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite (Severe) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events Systemic			

alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased Sleep (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Mild) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Moderate) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Moderate) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Severe) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability or Decreased Sleep (Severe) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Food allergy			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 99 (1.01%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Milk allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Allergy to arthropod sting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Beckwith-Wiedemann syndrome			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypersomnia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Subdural hygroma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Teething			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dry skin			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Erythema			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[47]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[48]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[49]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[50]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[51] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Tenderness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[52] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Tenderness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[53] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Tenderness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[54] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Tenderness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[55] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Tenderness (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[56] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Tenderness (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[57] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[58] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[59] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[60] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[61] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[62] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[63] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[64] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea alternative assessment type: Systematic subjects affected / exposed[65] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea alternative assessment type: Systematic subjects affected / exposed[66] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Swelling (Severe) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[67] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Any) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[68] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[69] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[70] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Mild) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[71] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[72] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[73] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[74] occurrences (all)	0 / 99 (0.00%) 0	0 / 97 (0.00%) 0	0 / 88 (0.00%) 0
Redness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[75]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[76]	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Ear infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Influenza			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection bacterial			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Viral infection			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Viral rash			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Herpangina			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 97 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC Group 2 (Term Infant) - 2 Year Follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 88 (1.14%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

Injection site erythema			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Developmental delay			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 88 (1.14%)		
occurrences (all)	1		
Fever ≥38 degree centigrade (°C) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever ≥38°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events Systemic			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever ≥38°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever ≥38°C but ≤39°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever ≥38°C but ≤39°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever ≥38°C but ≤39°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever >39°C but ≤40°C Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever >39°C but ≤40°C Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever >39°C but ≤40°C Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 88 (0.00%)		
occurrences (all)	0		
Fever >40°C Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used:			

Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 88 (0.00%)		
occurrences (all)	0		
Decreased Appetite (Severe) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 88 (0.00%)		
occurrences (all)	0		
Increased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events Systemic			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 88 (0.00%)		
occurrences (all)	0		
Increased Sleep (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 88 (0.00%)		
occurrences (all)	0		
Increased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 88 (0.00%)		
occurrences (all)	0		
Increased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 88 (0.00%)		
occurrences (all)	0		
Increased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[28] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[29] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[30] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[31] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[32] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[33] occurrences (all)	0 / 88 (0.00%) 0		
Increased Sleep (Severe) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[34] occurrences (all)	0 / 88 (0.00%) 0		
Irritability or Decreased Sleep (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[35] occurrences (all)	0 / 88 (0.00%) 0		
Irritability or Decreased Sleep (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[36] occurrences (all)	0 / 88 (0.00%) 0		
Irritability or Decreased Sleep (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	0 / 88 (0.00%) 0		
Irritability or Decreased Sleep (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	0 / 88 (0.00%) 0		
Irritability or Decreased Sleep (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability or Decreased Sleep (Mild) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability or Decreased Sleep (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability or Decreased Sleep (Moderate) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability or Decreased Sleep (Moderate) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability or Decreased Sleep (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 88 (0.00%)		
occurrences (all)	0		

Irritability or Decreased Sleep (Severe) Dose 2 Infant	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 88 (0.00%)		
occurrences (all)	0		
Irritability or Decreased Sleep (Severe) Dose 3 Infant	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 88 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Food allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Milk allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Allergy to arthropod sting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Investigations			
Cardiac murmur			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic			

disorders			
Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Hydrocele			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Beckwith-Wiedemann syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Hypersomnia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Subdural hygroma			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Loss of consciousness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Febrile convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			

Anaemia			
alternative dictionary used: MedDRA MedDRA (U			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Eye discharge			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Aphthous stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Constipation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Infantile colic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Umbilical hernia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Teething			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholelithiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Dermatitis diaper			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Dry skin			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Erythema			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[47]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[48]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[49]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[50]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[51]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[52]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[53]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[54]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[55]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Severe) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[56]	0 / 88 (0.00%)		
occurrences (all)	0		
Tenderness (Severe) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[57]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Any) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[58]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[59]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[60]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Mild) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[61]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[62]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[63]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[64]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea			
alternative assessment type: Systematic			
subjects affected / exposed[65]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions Local Rea			
alternative assessment type: Systematic			
subjects affected / exposed[66]	0 / 88 (0.00%)		
occurrences (all)	0		
Swelling (Severe) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[67]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Any) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[68]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Any) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[69]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Any) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[70]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Mild) Dose 1(infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[71]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Mild) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[72]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Mild) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[73]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Moderate) Dose 1 (infant and toddler dose)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[74]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Moderate) Dose 2 infant	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[75]	0 / 88 (0.00%)		
occurrences (all)	0		
Redness (Moderate) Dose 3 infant	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[76]	0 / 88 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acute sinusitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 88 (0.00%)		
occurrences (all)	0		
Bronchitis			
alternative assessment type:			

Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Ear infection				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Exanthema subitum				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Influenza				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Laryngitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Otitis media				
alternative assessment type: Systematic				

subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Otitis media acute				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Pharyngitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Pneumonia				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Respiratory tract infection bacterial				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Respiratory tract infection viral				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Rhinitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 88 (0.00%)			
occurrences (all)	0			

Urinary tract infection alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Viral infection alternative dictionary used: MedDRA MedDRA (U subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Viral rash alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Viral upper respiratory tract infection alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Bronchopneumonia alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Herpangina alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Tonsillitis alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite alternative assessment type: Systematic subjects affected / exposed occurrences (all)	 0 / 88 (0.00%) 0		

Notes:

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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