Clinical trial results:
Phase 2, Randomized, Active-Controlled, Double-Blind Trial Evaluating The Safety, Tolerability, And Immunogenicity Of A 13-Valent Pneumococcal Conjugate Vaccine In Healthy Infants Given With Routine Pediatric Vaccinations In Korea

Summary

EudraCT number	2008-004769-24
Trial protocol	Outside EU/EEA
Global end of trial date	11 December 2009

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	30 July 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-010

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00689351
WHO universal trial number (UTN)	-
Other trial identifiers	Alias ID: B1851001

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, clinicaltrials.gov_inquiries@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, clinicaltrials.gov_inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 August 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 December 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the pneumococcal immune responses induced by 13-valent pneumococcal conjugate vaccine (13vPnC) relative to the pneumococcal immune responses induced by 7 valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the infant series.
To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and adverse events (AEs).

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	22 July 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Korea, Republic of: 180
Worldwide total number of subjects	180
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	180
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:

Total 180 subjects were enrolled in the study. The study was conducted in Korea, "the Republic of" which started on 22 July 2008 and completed on 11 December 2009.

Period 1

Period 1 title	Infant Series
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC: Infant Series

Arm description:

Each subject was to receive 13vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 13vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 13vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.

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

Dosage and administration details:

13vPnC was administered at a dose of 0.5 milliliter (mL) at 2, 4, and 6 months of age (infant series).

Investigational medicinal product name	Diphtheria, tetanus, and acellular pertussis vaccine (DTaP)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

DTap was administered intramuscularly concomitantly with 13vPnC at 2, 4, and 6 months of age in the anterolateral muscle of the right thigh according to standard vaccination practice.

Investigational medicinal product name	Inactivated poliovirus vaccine (IPV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

IPV were to be administered 7 to 21 days after each dose of 13vPnC during the infant series according to standard vaccination practice.

Investigational medicinal product name	Haemophilus influenzae type b (Hib)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use

Dosage and administration details:

Hib vaccine were to be administered 7 to 21 days after each dose of 13vPnC during the infant series according to standard vaccination practice.

Investigational medicinal product name	Hepatitis B virus vaccine (HBV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

HBV was administered 7 to 21 days after dose 3 of 13vPnC according to standard vaccination practice.

Arm title	7vPnC: Infant Series

Arm description:

Each subject was to receive 7vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 7vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 7vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.

Arm type	Active comparator
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

7vPnC was administered at a dose of 0.5 mL at 2, 4, and 6 months of age (infant series).

Investigational medicinal product name	Diphtheria, tetanus, and acellular pertussis vaccine (DTaP)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

DTap was administered intramuscularly concomitantly with 7vPnC at 2, 4, and 6 months of age in the anterolateral muscle of the right thigh according to standard vaccination practice.

Investigational medicinal product name	Inactivated poliovirus vaccine (IPV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

IPV were to be administered 7 to 21 days after each dose of 7vPnC during the infant series according to standard vaccination practice.

Investigational medicinal product name	Haemophilus influenzae type b (Hib)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hib vaccine were to be administered 7 to 21 days after each dose of 7vPnC during the infant series according to standard vaccination practice.

Investigational medicinal product name	Hepatitis B virus vaccine (HBV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use

Dosage and administration details:

HBV was administered 7 to 21 days after dose 3 of 7vPnC according to standard vaccination practice.

Number of subjects in period 1	13vPnC: Infant Series	7vPnC: Infant Series
Started	91	89
Vaccinated Dose 1	88	89
Vaccinated Dose 2	86	88
Vaccinated Dose 3	85	88
Completed	85	88
Not completed	6	1
'Parent/legal guardian request '	5	-
Adverse Event	1	-
Lost to follow-up	-	1

Period 2

Period 2 title	After Infant Series
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC: After the Infant Series

Arm description:

Included subjects who received 13vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 13vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 13vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC: After the Infant Series

Arm description:

Included subjects who received 7vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 7vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 7vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	13vPnC: After the Infant Series	7vPnC: After the Infant Series
Started	85	88
Completed	84	88
Not completed	1	0
'Parent/legal guardian request '	1	-

Period 3	
Period 3 title	Toddler Dose
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor
Arms	
Are arms mutually exclusive?	Yes
Arm title	13vPnC: Toddler Dose
Arm description:	
13vPnC dose administered IM at 12 months of age (toddler dose).	
Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
13vPnC was administered at a dose of 0.5 mL at 12 months of age (toddler dose).	
Arm title	7vPnC: Toddler Dose
Arm description:	
7vPnC dose administered IM at 12 months of age (toddler dose).	
Arm type	Active comparator
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
7vPnC was administered at a dose of 0.5 mL at 12 months of age (toddler dose).

Number of subjects in period 3	13vPnC: Toddler Dose	7vPnC: Toddler Dose
Started	84	88
Completed	84	88

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC: Infant Series
Reporting group description:	
Each subject was to receive 13vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 13vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 13vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.	
Reporting group title	7vPnC: Infant Series
Reporting group description:	
Each subject was to receive 7vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 7vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 7vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.	

Reporting group values	13vPnC: Infant Series	7vPnC: Infant Series	Total
Number of subjects	91	89	180
Age categorical			
Units: Subjects			

Age continuous			
Units: months			
arithmetic mean	2.1	2.1	
standard deviation	± 0.3	± 0.2	-
Gender categorical			
Units: Subjects			
Female	45	39	84
Male	46	50	96

End points

End points reporting groups

Reporting group title	13vPnC: Infant Series
Reporting group description:	
Each subject was to receive 13vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 13vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 13vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.	
Reporting group title	7vPnC: Infant Series
Reporting group description:	
Each subject was to receive 7vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 7vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 7vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.	
Reporting group title	13vPnC: After the Infant Series
Reporting group description:	
Included subjects who received 13vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 13vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 13vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.	
Reporting group title	7vPnC: After the Infant Series
Reporting group description:	
Included subjects who received 7vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 7vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 7vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.	
Reporting group title	13vPnC: Toddler Dose
Reporting group description:	
13vPnC dose administered IM at 12 months of age (toddler dose).	
Reporting group title	7vPnC: Toddler Dose
Reporting group description:	
7vPnC dose administered IM at 12 months of age (toddler dose).	

Primary: Percentage of Subjects Achieving a Serotype-specific Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=) 0.35 Micrograms Per Milliliter (Mcg/mL) Measured 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving a Serotype-specific Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=) 0.35 Micrograms Per Milliliter (Mcg/mL) Measured 1 Month After the Infant Series[1]
End point description:	
Percentage of subjects achieving predefined antibody threshold ≥0.35 Mcg/mL along with the corresponding 95 percent (%) confidence interval (CI) was calculated 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). Evaluable Infant Immunogenicity population: subjects who were 41 to 99 days of age (inclusive) on the day of the first vaccination, who had treatments as randomized (all expected doses) and at least 1 valid and determinate assay result for proposed analysis and no major protocol violation.	
End point type	Primary
End point timeframe:	
1 month after the infant series (7 months of age)	

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 reported for this endpoint.

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	85		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 4	100 (95.7 to 100)	100 (95.8 to 100)		
Serotype 6B	98.8 (93.5 to 100)	100 (95.8 to 100)		
Serotype 9V	100 (95.7 to 100)	100 (95.8 to 100)		
Serotype 14	100 (95.7 to 100)	100 (95.8 to 100)		
Serotype 18C	100 (95.7 to 100)	100 (95.8 to 100)		
Serotype 19F	97.6 (95.7 to 100)	98.8 (93.6 to 100)		
Serotype 23F	98.8 (91.6 to 99.7)	98.8 (93.6 to 100)		
Serotype 1	100 (93.5 to 100)	2.4 (0.3 to 8.2)		
Serotype 3	100 (95.7 to 100)	2.4 (0.3 to 8.2)		
Serotype 5	100 (95.7 to 100)	57.5 (45.9 to 68.5)		
Serotype 6A	97.6 (95.7 to 100)	72.3 (61.4 to 81.6)		
Serotype 7F	100 (91.6 to 99.7)	4.8 (1.3 to 11.7)		
Serotype 19A	100 (95.7 to 100)	100 (95.6 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a Serotype-specific IgG Antibody Level (>=) 0.35 Mcg/mL Measured 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving a Serotype-specific IgG Antibody Level (>=) 0.35 Mcg/mL Measured 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving predefined antibody threshold ≥0.35Mcg/mL along with the corresponding 95% CI was calculated 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). Exact 2-sided CI was based on the observed percentage of subjects. Evaluable Toddler Immunogenicity population:41-99 days old inclusive on day of first vaccination, 365-395 days old inclusive at toddler dose, had all treatments as randomized, blood drawn within specified timeframes, at least 1 valid and determinate assay result for proposed analysis, and no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose (13 months of age)

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	84		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype 4	100 (95.5 to 100)	100 (95.7 to 100)		
Serotype 6B	100 (95.5 to 100)	100 (95.7 to 100)		
Serotype 9V	100 (95.5 to 100)	100 (95.7 to 100)		
Serotype 14	98.7 (93.1 to 100)	100 (95.7 to 100)		
Serotype 18C	100 (95.5 to 100)	100 (95.7 to 100)		
Serotype 19F	100 (95.5 to 100)	100 (95.7 to 100)		
Serotype 23F	100 (95.5 to 100)	100 (95.7 to 100)		
Serotype 1	100 (95.5 to 100)	1.3 (0 to 6.9)		
Serotype 3	100 (95.5 to 100)	12 (5.9 to 21)		
Serotype 5	100 (95.5 to 100)	92.4 (84.2 to 97.2)		
Serotype 6A	98.8 (93.2 to 100)	100 (95.7 to 100)		
Serotype 7F	100 (95.4 to 100)	23.6 (13.2 to 37)		
Serotype 19A	100 (95.5 to 100)	98.8 (93.5 to 100)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Concentration (GMC) of Serotype-specific IgG Antibody 1 Month After the Infant Series

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

End point description:

Antibody GMC along with corresponding 2-sided 95% CI for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Geometric mean concentrations (GMCs) were calculated using all subjects with available data for the specified blood draw. Evaluable Infant Immunogenicity Population.

End point type	Other pre-specified

End point timeframe:

1 month after the infant series (7 months of age)

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	85		
Units: Mcg/mL (micrograms per milliliter)				
geometric mean (confidence interval 95%)				
Serotype 4	5.4 (4.62 to 6.3)	6.97 (5.94 to 8.18)		
Serotype 6B	5.71 (4.64 to 7.03)	4.88 (3.96 to 6.01)		
Serotype 9V	3.33 (2.9 to 3.83)	3.78 (3.31 to 4.33)		
Serotype 14	14.83 (12.38 to 17.77)	16.29 (13.36 to 19.85)		
Serotype 18C	4.57 (3.98 to 5.24)	4.73 (4.09 to 5.47)		
Serotype 19F	3.88 (3.18 to 4.72)	4.2 (3.55 to 4.96)		
Serotype 23F	4.29 (3.56 to 5.16)	4.11 (3.4 to 4.98)		
Serotype 1	7.44 (6.25 to 8.85)	0.02 (0.02 to 0.03)		
Serotype 3	1.6 (1.35 to 1.89)	0.04 (0.03 to 0.05)		
Serotype 5	5.06 (4.37 to 5.85)	0.39 (0.3 to 0.49)		
Serotype 6A	5.73 (4.64 to 7.07)	0.64 (0.49 to 0.82)		
Serotype 7F	6.97 (6.07 to 8)	0.04 (0.03 to 0.05)		
Serotype 19A	5.94 (5.13 to 6.89)	2.65 (2.29 to 3.06)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.97

Statistical analysis title	Serotype 6B

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	7vPnC: Infant Series v 13vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.57

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.07

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	7vPnC: Infant Series v 13vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.19

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.18

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.19

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.36

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	329.44

Confidence interval	
level	95 %
sides	2-sided
lower limit	242.98
upper limit	446.67

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	40.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.27
upper limit	54.97

Statistical analysis title	Serotype 5

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	13.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.92
upper limit	17.34

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	9.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.46
upper limit	12.56

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	165.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	122.95
upper limit	223.85

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	2.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.83
upper limit	2.75

Other pre-specified: Geometric Mean Concentration (GMC) of Serotype-specific IgG Antibody 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) of Serotype-specific IgG Antibody 1 Month After the Toddler Dose

End point description:

Antibody GMC along with corresponding 2-sided 95% CI for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Geometric mean concentrations (GMCs) were calculated using all subjects with available data for the specified blood draw. Evaluable Toddler Immunogenicity Population.

End point type	Other pre-specified

End point timeframe:

1 month after the Toddler Dose (13 months of age)

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	84		
Units: Mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	6.46 (5.29 to 7.9)	8.25 (6.88 to 9.89)		
Serotype 6B	16.81 (14.36 to 19.68)	15.14 (11.91 to 19.25)		
Serotype 9V	4.59 (3.91 to 5.38)	4.83 (4.12 to 5.67)		
Serotype 14	11.51 (9.59 to 13.8)	15.64 (13.07 to 18.72)		
Serotype 18C	6.86 (5.67 to 8.29)	7.44 (6.27 to 8.83)		
Serotype 19F	7.75 (6.3 to 9.53)	5.35 (4.52 to 6.33)		
Serotype 23F	10.95 (8.77 to 13.66)	10.44 (8.6 to 12.68)		
Serotype 1	9.29 (7.65 to 11.28)	0.04 (0.03 to 0.05)		
Serotype 3	1.65 (1.4 to 1.95)	0.1 (0.08 to 0.13)		

Serotype 5	8.92 (7.62 to 10.45)	1.31 (1.09 to 1.56)		
Serotype 6A	13.58 (11.28 to 16.36)	3.33 (2.67 to 4.14)		
Serotype 7F	11.17 (9.33 to 13.37)	0.1 (0.07 to 0.14)		
Serotype 19A	10.12 (8.55 to 11.98)	2.38 (2.04 to 2.78)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).	
Comparison groups	7vPnC: Toddler Dose v 13vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.02

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.48

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.19

Statistical analysis title	Serotype 14
Statistical analysis description:	
Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.95

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.19

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.88

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.4

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	234.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	176.33
upper limit	311.41

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	16.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.19
upper limit	22.69

Statistical analysis title	Serotype 5

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	6.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.39
upper limit	8.67

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC). Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	4.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.07
upper limit	5.43

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	110.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	77.09
upper limit	159.59

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of geometric means (13vPnC, 7vPnC).Geometric mean ratio computed from back transformation using Student t distribution for the mean difference of the measures on the log scale. CI 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 (13vPnC, 7vPnC).

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other
Method	Student t distribution
Parameter estimate	Ratio of geometric means
Point estimate	4.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.39
upper limit	5.33

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions: Infant Series Dose 1 (2 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions: Infant Series Dose 1 (2 Months of Age)

End point description:

Pre-specified local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (greater than [>] 7.0 cm). Subjects may be represented in more than 1 category. Safety population: All subjects who received at least 1 dose of the study vaccine. Here "n" = number of subjects reporting the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose 1 (2 months of age)

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75[2]	79[3]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=23,26)	31.9	34.2		
Tenderness: Significant (n=6,2)	8.8	2.8		
Swelling: Any (n=14,18)	19.7	24.7		
Swelling: Mild (n=8,18)	11.6	24.7		
Swelling: Moderate (n=7,4)	10.1	5.7		
Redness: Any (n=27,22)	37.5	29.3		
Redness: Mild (n=23,19)	32.9	25.3		
Redness: Moderate (n=4,3)	5.8	4.3		

Notes:

[2] - N = Number of subjects reporting yes for at least 1 day or no for all days

[3] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Tenderness: Any
Statistical analysis description: Comparison between treatments for any tenderness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.862
Method	Fisher exact

Statistical analysis title	Tenderness: Significant
Statistical analysis description: Comparison between treatments for significant tenderness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.157
Method	Fisher exact

Statistical analysis title	Swelling: Any
Statistical analysis description: Comparison between treatments for any swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.55
Method	Fisher exact

Statistical analysis title	Swelling: Mild
Statistical analysis description: Comparison between treatments for mild swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.052
Method	Fisher exact

Statistical analysis title	Swelling: Moderate
Statistical analysis description: Comparison between treatments for moderate swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.366
Method	Fisher exact

Statistical analysis title	Redness: Any
Statistical analysis description: Comparison between treatments for any redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.301
Method	Fisher exact

Statistical analysis title	Redness: Mild
Statistical analysis description: Comparison between treatments for mild redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.362
Method	Fisher exact

Statistical analysis title	Redness: Moderate

Statistical analysis description:

Comparison between treatments for moderate redness.

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.718
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions: Infant Series Dose 2 (4 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions: Infant Series Dose 2 (4 Months of Age)

End point description:

Pre-specified local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 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; Here "n" = number of subjects reporting the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose 2 (4 months of age)

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62[4]	68[5]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=23,24)	38.3	37.5		
Tenderness: Significant (n=0,3)	0	5		
Swelling: Any (n=22,18)	35.5	28.6		
Swelling: Mild (n=18,15)	29.5	24.6		
Swelling: Moderate (n=4,4)	7.1	6.6		
Redness: Any (n=20,25)	32.8	38.5		
Redness: Mild (n=18,24)	29.5	36.9		
Redness: Moderate (n=4,3)	7.1	5.1		

Notes:
[4] - N = Number of subjects reporting yes for at least 1 day or no for all days
[5] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Tenderness: Any
Statistical analysis description: Comparison between treatments for any tenderness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Tenderness: Significant
Statistical analysis description: Comparison between treatments for significant tenderness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.245
Method	Fisher exact

Statistical analysis title	Swelling: Any
Statistical analysis description: Comparison between treatments for any swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.447
Method	Fisher exact

Statistical analysis title	Swelling: Mild
Statistical analysis description: Comparison between treatments for mild swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.684
Method	Fisher exact

Statistical analysis title	Swelling: Moderate
Statistical analysis description: Comparison between treatments for moderate swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Redness: Any
Statistical analysis description: Comparison between treatments for any redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.578
Method	Fisher exact

Statistical analysis title	Redness: Mild
Statistical analysis description: Comparison between treatments for mild redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.451
Method	Fisher exact

Statistical analysis title	Redness: Moderate
Statistical analysis description: Comparison between treatments for moderate redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.712
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions: Infant Series Dose 3 (6 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions: Infant Series Dose 3 (6 Months of Age)

End point description:

Pre-specified local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 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; Here "n" = number of subjects reporting the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose 3 (6 months of age)

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66[6]	64[7]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=15,16)	23.4	27.1		
Tenderness: Significant (n=0,1)	0	1.9		
Swelling: Any (n=18,14)	27.7	23.3		
Swelling: Mild (n=13,13)	21	22		
Swelling: Moderate (n=7,4)	11.3	7		
Redness: Any (n=19,16)	30.2	26.2		
Redness: Mild (n=12,15)	20	25		
Redness: Moderate (n=7,3)	11.5	5.6		

Notes:

[6] - N = Number of subjects reporting yes for at least 1 day or no for all days

[7] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Tenderness: Any

Statistical analysis description:

Comparison between treatments for any tenderness.

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.681
Method	Fisher exact

Statistical analysis title	Tenderness: Significant
Statistical analysis description: Comparison between treatments for significant tenderness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.482
Method	Fisher exact

Statistical analysis title	Swelling: Any
Statistical analysis description: Comparison between treatments for any swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.683
Method	Fisher exact

Statistical analysis title	Swelling: Mild
Statistical analysis description: Comparison between treatments for mild swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Swelling: Moderate
Statistical analysis description: Comparison between treatments for moderate swelling.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.533
Method	Fisher exact

Statistical analysis title	Redness: Any
Statistical analysis description: Comparison between treatments for any redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.692
Method	Fisher exact

Statistical analysis title	Redness: Mild
Statistical analysis description: Comparison between treatments for mild redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.662
Method	Fisher exact

Statistical analysis title	Redness: Moderate
Statistical analysis description: Comparison between treatments for moderate redness.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.331
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions: Toddler Dose (12 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions: Toddler Dose (12 Months of Age)

End point description:

Pre-specified local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 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; Here "n" = number of participants reporting the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Within 4 days after toddler dose (12 months of age)

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57[8]	57[9]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=19,14)	33.9	25.9		
Tenderness: Significant (n=3,1)	5.9	2		
Swelling: Any (n=11,10)	22.4	18.9		
Swelling: Mild (n=4,7)	8.2	13.5		
Swelling: Moderate (n=9,4)	18.4	7.8		
Swelling: Severe (n=1,0)	2	0		
Redness: Any (n=15,12)	28.8	22.2		
Redness: Mild (n=9,10)	17.6	18.5		
Redness: Moderate (n=8,3)	16	6		

Notes:

[8] - N = Number of subjects reporting yes for at least 1 day or no for all days

[9] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Tenderness: Any

Statistical analysis description:

Comparison between treatments for any tenderness.

Comparison groups	7vPnC: Toddler Dose v 13vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.409
Method	Fisher exact

Statistical analysis title	Tenderness: Significant

Statistical analysis description:

Comparison between treatments for significant tenderness.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.617
Method	Fisher exact

Statistical analysis title	Swelling: Any
Statistical analysis description: Comparison between treatments for any swelling.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.807
Method	Fisher exact

Statistical analysis title	Swelling: Mild
Statistical analysis description: Comparison between treatments for mild swelling.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.527
Method	Fisher exact

Statistical analysis title	Swelling: Moderate
Statistical analysis description: Comparison between treatments for moderate swelling.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.144
Method	Fisher exact

Statistical analysis title	Swelling: Severe
Statistical analysis description: Comparison between treatments for severe swelling.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.495
Method	Fisher exact

Statistical analysis title	Redness: Any
Statistical analysis description: Comparison between treatments for any redness.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.506
Method	Fisher exact

Statistical analysis title	Redness: Mild
Statistical analysis description: Comparison between treatments for mild redness.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Redness: Moderate
Statistical analysis description: Comparison between treatments for moderate redness.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.2
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events: Infant Series Dose 1 (2 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events: Infant Series Dose 1 (2 Months of Age)

End point description:

Pre-specified systemic events (any fever ≥ 38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety; Here "n" = number of subjects reporting the event.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose 1 (2 months of age)

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83[10]	86[11]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 degrees C but ≤39 degrees C (n=11,9)	15.9	12.5		
Decreased appetite (n=23,22)	32.4	28.9		
Irritability (n=38,56)	49.4	70.9		
Increased sleep (n=37,30)	49.3	39		
Decreased sleep (n=28,38)	37.8	50		

Notes:

[10] - N = Number of subjects reporting yes for at least 1 day or no for all days

[11] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Fever ≥38 degrees C but ≤39 degrees C

Statistical analysis description:

Comparison between treatments for fever ≥38 degrees C but but less than or equal to (≤)39 degrees C.

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.633
Method	Fisher exact

Statistical analysis title	Decreased appetite

Statistical analysis description:

Comparison between treatments for decreased appetite.

Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.721
Method	Fisher exact

Statistical analysis title	Irritability
Statistical analysis description: Comparison between treatments for irritability.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.009
Method	Fisher exact

Statistical analysis title	Increased sleep
Statistical analysis description: Comparison between treatments for increased sleep.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.253
Method	Fisher exact

Statistical analysis title	Decreased sleep
Statistical analysis description: Comparison between treatments for decreased sleep.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	169
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.143
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events: Infant Series Dose 2 (4 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events: Infant Series Dose 2 (4 Months of Age)
End point description: Pre-specified systemic events (any fever ≥ 38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety; Here "n" = number of subjects reporting the event.	
End point type	Other pre-specified
End point timeframe: Within 4 days after dose 2 (4 months of age)	

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64[12]	72[13]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 degrees C but ≤39 degrees C (n=6,8)	10.9	13.1		
Decreased appetite (n=16,28)	27.1	44.4		
Irritability (n=25,36)	40.3	53.7		
Increased sleep (n=17,16)	28.8	26.2		
Decreased sleep (n=18,27)	30	40.9		

Notes:

[12] - N = Number of subjects reporting yes for at least 1 day or no for all days

[13] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Fever ≥38 degrees C but ≤39 degrees C
Statistical analysis description: Comparison between treatments for fever ≥38 degrees C but ≤39 degrees C.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.781
Method	Fisher exact

Statistical analysis title	Decreased appetite
Statistical analysis description: Comparison between treatments for decreased appetite.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.06
Method	Fisher exact

Statistical analysis title	Irritability
Statistical analysis description: Comparison between treatments for irritability.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series

Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.159
Method	Fisher exact

Statistical analysis title	Increased sleep
Statistical analysis description:	
Comparison between treatments for increased sleep.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.839
Method	Fisher exact

Statistical analysis title	Decreased sleep
Statistical analysis description:	
Comparison between treatments for decreased sleep.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.264
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events: Infant Series Dose 3 (6 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events: Infant Series Dose 3 (6 Months of Age)
End point description:	
Pre-specified systemic events (any fever ≥ 38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety; Here "n" = number of subjects reporting the event.	
End point type	Other pre-specified
End point timeframe:	
Within 4 days after dose 3 (6 months of age)	

End point values	13vPnC: Infant Series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65[14]	64[15]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 degrees C but ≤39 degrees C (n=8,5)	13.6	9.3		
Fever >39 degrees C but ≤40 degrees C (n=0,1)	0	2		
Decreased appetite (n=14,16)	23	28.1		
Irritability (n=13,25)	21	41.7		
Increased sleep (n=18,12)	29.5	21.1		
Decreased sleep (n=10,17)	16.4	29.3		

Notes:

[14] - N = Number of subjects reporting yes for at least 1 day or no for all days

[15] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Fever ≥38 degrees C but ≤39 degrees C
Statistical analysis description:	
Comparison between treatments for fever ≥38 degrees C but ≤39 degrees C.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.563
Method	Fisher exact

Statistical analysis title	Fever >39 degrees C but ≤40 degrees C
Statistical analysis description:	
Comparison between treatments for fever >39 degrees C but ≤40 degrees C.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.468
Method	Fisher exact

Statistical analysis title	Decreased appetite
Statistical analysis description:	
Comparison between treatments for decreased appetite.	
Comparison groups	7vPnC: Infant Series v 13vPnC: Infant Series

Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.535
Method	Fisher exact

Statistical analysis title	Irritability
Statistical analysis description: Comparison between treatments for irritability.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.019
Method	Fisher exact

Statistical analysis title	Increased sleep
Statistical analysis description: Comparison between treatments for increased sleep.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.398
Method	Fisher exact

Statistical analysis title	Decreased sleep
Statistical analysis description: Comparison between treatments for decreased sleep.	
Comparison groups	13vPnC: Infant Series v 7vPnC: Infant Series
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.125
Method	Fisher exact

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events: Toddler Dose (12 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events: Toddler Dose (12 Months of Age)

End point description:

Pre-specified systemic events (any fever ≥ 38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety; Here "n" = number of subjects reporting the event.

End point type	Other pre-specified

End point timeframe:

Within 4 days after toddler dose (12 months of age)

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64[16]	65[17]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 degrees C but ≤39 degrees C (n=7,10)	13.7	19.6		
Fever >39 degrees C but ≤40 degrees C (n=1,0)	2	0		
Decreased appetite (n=13,15)	22.8	27.8		
Irritability (n=18,21)	30.5	37.5		
Increased sleep (n=11,8)	21.2	15.4		
Decreased sleep (n=11,20)	20.4	34.5		

Notes:

[16] - N = Number of subjects reporting yes for at least 1 day or no for all days

[17] - N = Number of subjects reporting yes for at least 1 day or no for all days

Statistical analyses

Statistical analysis title	Fever ≥38 degrees C but ≤39 degrees C

Statistical analysis description:

Comparison between treatments for fever ≥38 degrees C but ≤39 degrees C.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.596
Method	Fisher exact

Statistical analysis title	Fever >39 degrees C but ≤40 degrees C

Statistical analysis description:

Comparison between treatments for fever >39 degrees C but ≤40 degrees C.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose

Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Decreased appetite
Statistical analysis description: Comparison between treatments for decreased appetite.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.633
Method	Fisher exact

Statistical analysis title	Irritability
Statistical analysis description: Comparison between treatments for irritability.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.439
Method	Fisher exact

Statistical analysis title	Increased sleep
Statistical analysis description: Comparison between treatments for increased sleep.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.613
Method	Fisher exact

Statistical analysis title	Decreased sleep
Statistical analysis description: Comparison between treatments for decreased sleep.	
Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose

Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.138
Method	Fisher exact

Adverse events information

Timeframe for reporting adverse events:

Baseline through 1 Month after last study vaccination (13 Months). Local reactions and systemic events assessed within 4 days of dose: Infant Series Dose 1=2 months of age; Dose 2=4 months of age; Dose 3=6 months of age; Toddler Dose=12 months of age.

Adverse event reporting additional description:

An Adverse Event (AE) term may be reported as both serious and non-serious AE, but are distinct events.AE may=serious for 1 subject and=non-serious for another subject or may have experienced both a serious and non-serious episode of the same event. LR & SE to be assessed only for infant series and toddler dose groups. For MedDRA V 0.0 is captured.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	Infant Series 13vPnC

Reporting group description:

Each subject was to receive 13vPnC 0.5 mL dose administered IM at each of the 3 vaccination visits (2, 4, and 6-month visits). DTaP was to be administered concomitantly with 13vPnC at 2, 4, and 6 months of age. In addition, IPV and Hib vaccine were to be administered 7 to 21 days after each dose of 13vPnC during the infant series, and HBV was administered 7 to 21 days after dose 3.

Reporting group title	Infant Series 7vPnC

Reporting group description:

Each subject was to receive 7vPnC 0.5 mL dose administered IM at at each of the 3 vaccination visits (2, 4, and 6-month visits). DTaP was to be administered concomitantly with 7vPnC at 2, 4, and 6 months of age. In addition, IPV and Hib vaccine were to be administered 7 to 21 days after each dose of 7vPnC during the infant series, HBV was administered 7 to 21 days after dose 3.

Reporting group title	After the Infant Series 13vPnC

Reporting group description:

Included subjects who received 13vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 13vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 13vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.

Reporting group title	After the Infant Series 7vPnC

Reporting group description:

Included subjects who received 7vPnC at each of the 3 vaccination visits (2, 4, and 6month visits); Diptheria, tetanus, and acellular pertussis vaccine (DTaP) administered concomitantly with 7vPnC at 2, 4, and 6 months of age; inactivated poliovirus vaccine (IPV) and Haemophilus influenzae type b (Hib) vaccine 7 to 21 days after each dose of 7vPnC during the infant series; and hepatitis B virus vaccine (HBV) 7 to 21 days after dose 3.

Reporting group title	Toddler Dose 13vPnC

Reporting group description:

13vPnC 0.5mL dose administered IM at 12 months of age (toddler dose).

Reporting group title	Toddler Dose 7vPnC

Reporting group description:

7vPnC 0.5mL dose administered IM at 12 months of age (toddler dose).

Serious adverse events	Infant Series 13vPnC	Infant Series 7vPnC	After the Infant Series 13vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 88 (9.09%)	9 / 89 (10.11%)	9 / 88 (10.23%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	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
General disorders and administration site conditions			
Soft tissue inflammation			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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			
Diarrhoea			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	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
Inguinal hernia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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			

Bronchiolitis			
subjects affected / exposed	2 / 88 (2.27%)	4 / 89 (4.49%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 88 (3.41%)	1 / 89 (1.12%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 88 (0.00%)	2 / 89 (2.25%)	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
Bronchitis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	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
Gastroenteritis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	3 / 88 (3.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki's disease			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (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
Otitis media acute			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Herpangina			

subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Adenovirus infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Bacterial infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Exanthema subitum			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Hand-foot-and-mouth			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Influenza			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Rhinitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Tonsillitis			

subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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
Pharyngitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (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			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (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

Serious adverse events	After the Infant Series 7vPnC	Toddler Dose 13vPnC	Toddler Dose 7vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 89 (13.48%)	3 / 84 (3.57%)	3 / 88 (3.41%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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
General disorders and administration site conditions			
Soft tissue inflammation			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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			

subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Pneumonia			
subjects affected / exposed	1 / 89 (1.12%)	1 / 84 (1.19%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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			
subjects affected / exposed	1 / 89 (1.12%)	1 / 84 (1.19%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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

Gastroenteritis			
subjects affected / exposed	2 / 89 (2.25%)	1 / 84 (1.19%)	0 / 88 (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
Kawasaki's disease			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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
Otitis media acute			
subjects affected / exposed	3 / 89 (3.37%)	0 / 84 (0.00%)	0 / 88 (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
Herpangina			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Adenovirus infection			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Bacterial infection			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Exanthema subitum			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Hand-foot-and-mouth			

subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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
Influenza			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Rhinitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Tonsillitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (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
Pharyngitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (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

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

Non-serious adverse events	Infant Series 13vPnC	Infant Series 7vPnC	After the Infant Series 13vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	78 / 88 (88.64%)	75 / 89 (84.27%)	18 / 88 (20.45%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	8 / 88 (9.09%)	4 / 89 (4.49%)	0 / 88 (0.00%)
occurrences (all)	8	4	0

Injection site erythema			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Fever ≥ 38 degrees C but ≤ 39 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	11 / 69 (15.94%)	9 / 72 (12.50%)	0 / 88 (0.00%)
occurrences (all)	11	9	0
Fever ≥ 38 degrees C but ≤ 39 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	6 / 55 (10.91%)	8 / 61 (13.11%)	0 / 88 (0.00%)
occurrences (all)	6	8	0
Fever ≥ 38 degrees C but ≤ 39 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	8 / 59 (13.56%)	5 / 54 (9.26%)	0 / 88 (0.00%)
occurrences (all)	8	5	0
Fever > 39 degrees C but ≤ 40 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 67 (0.00%)	0 / 70 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever > 39 degrees C but ≤ 40 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 58 (0.00%)	1 / 51 (1.96%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	23 / 71 (32.39%)	22 / 76 (28.95%)	0 / 88 (0.00%)
occurrences (all)	23	22	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	16 / 59 (27.12%)	28 / 63 (44.44%)	0 / 88 (0.00%)
occurrences (all)	16	28	0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	14 / 61 (22.95%)	16 / 57 (28.07%)	0 / 88 (0.00%)
occurrences (all)	14	16	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	38 / 77 (49.35%)	56 / 79 (70.89%)	0 / 88 (0.00%)
occurrences (all)	38	56	0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	25 / 62 (40.32%)	36 / 67 (53.73%)	0 / 88 (0.00%)
occurrences (all)	25	36	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[11]	13 / 62 (20.97%)	25 / 60 (41.67%)	0 / 88 (0.00%)
occurrences (all)	13	25	0
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	37 / 75 (49.33%)	30 / 77 (38.96%)	0 / 88 (0.00%)
occurrences (all)	37	30	0
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	17 / 59 (28.81%)	16 / 61 (26.23%)	0 / 88 (0.00%)
occurrences (all)	17	16	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	18 / 61 (29.51%)	12 / 57 (21.05%)	0 / 88 (0.00%)
occurrences (all)	18	12	0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	28 / 74 (37.84%)	38 / 76 (50.00%)	0 / 88 (0.00%)
occurrences (all)	28	38	0
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	18 / 60 (30.00%)	27 / 66 (40.91%)	0 / 88 (0.00%)
occurrences (all)	18	27	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[17]	10 / 61 (16.39%)	17 / 58 (29.31%)	0 / 88 (0.00%)
occurrences (all)	10	17	0
Immune system disorders			
Atopy			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Perineal fistula			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	16 / 88 (18.18%)	16 / 89 (17.98%)	1 / 88 (1.14%)
occurrences (all)	18	20	1
Cough			
subjects affected / exposed	11 / 88 (12.50%)	17 / 89 (19.10%)	2 / 88 (2.27%)
occurrences (all)	12	21	2
Productive cough			
subjects affected / exposed	3 / 88 (3.41%)	2 / 89 (2.25%)	0 / 88 (0.00%)
occurrences (all)	3	2	0
Nasal congestion			
subjects affected / exposed	2 / 88 (2.27%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	3	1	0
Dyspnoea			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Grunting			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Asthma			

subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Upper airway obstruction			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Investigations			
Urine output decreased			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Joint sprain			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Mouth injury			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic			

disorders			
Hydrocele			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Middle ear effusion			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Otorrhoea			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	4 / 88 (4.55%)	2 / 89 (2.25%)	0 / 88 (0.00%)
occurrences (all)	4	2	0
Dacryostenosis acquired			
subjects affected / exposed	2 / 88 (2.27%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	2	0	0
Blepharitis			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Entropion			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Eye discharge			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	10 / 88 (11.36%)	10 / 89 (11.24%)	3 / 88 (3.41%)
occurrences (all)	12	11	3
Vomiting			
subjects affected / exposed	2 / 88 (2.27%)	3 / 89 (3.37%)	0 / 88 (0.00%)
occurrences (all)	3	4	0
Constipation			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Intussusception			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Regurgitation			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	8 / 88 (9.09%)	8 / 89 (8.99%)	2 / 88 (2.27%)
occurrences (all)	8	9	2
Eczema			
subjects affected / exposed	7 / 88 (7.95%)	3 / 89 (3.37%)	0 / 88 (0.00%)
occurrences (all)	7	3	0
Dermatitis diaper			
subjects affected / exposed	4 / 88 (4.55%)	2 / 89 (2.25%)	0 / 88 (0.00%)
occurrences (all)	5	2	0
Rash			
subjects affected / exposed	1 / 88 (1.14%)	6 / 89 (6.74%)	2 / 88 (2.27%)
occurrences (all)	1	6	2
Dermatitis			

subjects affected / exposed	2 / 88 (2.27%)	3 / 89 (3.37%)	0 / 88 (0.00%)
occurrences (all)	2	3	0
Urticaria			
subjects affected / exposed	0 / 88 (0.00%)	3 / 89 (3.37%)	0 / 88 (0.00%)
occurrences (all)	0	3	0
Heat rash			
subjects affected / exposed	2 / 88 (2.27%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	2	0	0
Rash papular			
subjects affected / exposed	1 / 88 (1.14%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	1	1	0
Skin erosion			
subjects affected / exposed	1 / 88 (1.14%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	1	1	0
Dermal cyst			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Eczema infantile			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Intertrigo			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Rash vesicular			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Tenderness (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[18]	23 / 72 (31.94%)	26 / 76 (34.21%)	0 / 88 (0.00%)
occurrences (all)	23	26	0
Tenderness (any); Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	23 / 60 (38.33%)	24 / 64 (37.50%)	0 / 88 (0.00%)
occurrences (all)	23	24	0
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	15 / 64 (23.44%)	16 / 59 (27.12%)	0 / 88 (0.00%)
occurrences (all)	15	16	0
Tenderness (significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	6 / 68 (8.82%)	2 / 72 (2.78%)	0 / 88 (0.00%)
occurrences (all)	6	2	0
Tenderness (significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 55 (0.00%)	3 / 60 (5.00%)	0 / 88 (0.00%)
occurrences (all)	0	3	0
Tenderness (significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 58 (0.00%)	1 / 54 (1.85%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Swelling (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[24]	14 / 71 (19.72%)	18 / 73 (24.66%)	0 / 88 (0.00%)
occurrences (all)	14	18	0
Swelling (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[25]	22 / 62 (35.48%)	18 / 63 (28.57%)	0 / 88 (0.00%)
occurrences (all)	22	18	0
Swelling (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[26]	18 / 65 (27.69%)	14 / 60 (23.33%)	0 / 88 (0.00%)
occurrences (all)	18	14	0
Swelling (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[27]	8 / 69 (11.59%)	18 / 73 (24.66%)	0 / 88 (0.00%)
occurrences (all)	8	18	0
Swelling (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[28]	18 / 61 (29.51%)	15 / 61 (24.59%)	0 / 88 (0.00%)
occurrences (all)	18	15	0
Swelling (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[29]	13 / 62 (20.97%)	13 / 59 (22.03%)	0 / 88 (0.00%)
occurrences (all)	13	13	0
Swelling (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[30]	7 / 69 (10.14%)	4 / 70 (5.71%)	0 / 88 (0.00%)
occurrences (all)	7	4	0
Swelling (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	4 / 56 (7.14%)	4 / 61 (6.56%)	0 / 88 (0.00%)
occurrences (all)	4	4	0
Swelling (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	7 / 62 (11.29%)	4 / 57 (7.02%)	0 / 88 (0.00%)
occurrences (all)	7	4	0
Swelling (severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 67 (0.00%)	0 / 70 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Redness (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	27 / 72 (37.50%)	22 / 75 (29.33%)	0 / 88 (0.00%)
occurrences (all)	27	22	0
Redness (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	20 / 61 (32.79%)	25 / 65 (38.46%)	0 / 88 (0.00%)
occurrences (all)	20	25	0
Redness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[36]	19 / 63 (30.16%)	16 / 61 (26.23%)	0 / 88 (0.00%)
occurrences (all)	19	16	0
Redness (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[37]	23 / 70 (32.86%)	19 / 75 (25.33%)	0 / 88 (0.00%)
occurrences (all)	23	19	0
Redness (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[38]	18 / 61 (29.51%)	24 / 65 (36.92%)	0 / 88 (0.00%)
occurrences (all)	18	24	0
Redness (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[39]	12 / 60 (20.00%)	15 / 60 (25.00%)	0 / 88 (0.00%)
occurrences (all)	12	15	0
Redness (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[40]	4 / 69 (5.80%)	3 / 70 (4.29%)	0 / 88 (0.00%)
occurrences (all)	4	3	0
Redness (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[41]	4 / 56 (7.14%)	3 / 59 (5.08%)	0 / 88 (0.00%)
occurrences (all)	4	3	0
Redness (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[42]	7 / 61 (11.48%)	3 / 54 (5.56%)	0 / 88 (0.00%)
occurrences (all)	7	3	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	24 / 88 (27.27%)	30 / 89 (33.71%)	3 / 88 (3.41%)
occurrences (all)	37	51	3
Bronchiolitis			
subjects affected / exposed	17 / 88 (19.32%)	9 / 89 (10.11%)	0 / 88 (0.00%)
occurrences (all)	27	12	0
Nasopharyngitis			
subjects affected / exposed	11 / 88 (12.50%)	17 / 89 (19.10%)	3 / 88 (3.41%)
occurrences (all)	13	20	3
Bronchitis			
subjects affected / exposed	10 / 88 (11.36%)	10 / 89 (11.24%)	2 / 88 (2.27%)
occurrences (all)	12	16	3
Gastroenteritis			
subjects affected / exposed	12 / 88 (13.64%)	7 / 89 (7.87%)	0 / 88 (0.00%)
occurrences (all)	12	9	0
Otitis media acute			
subjects affected / exposed	9 / 88 (10.23%)	5 / 89 (5.62%)	0 / 88 (0.00%)
occurrences (all)	13	5	0
Pharyngotonsillitis			
subjects affected / exposed	4 / 88 (4.55%)	1 / 89 (1.12%)	1 / 88 (1.14%)
occurrences (all)	8	1	1
Acute tonsillitis			
subjects affected / exposed	1 / 88 (1.14%)	2 / 89 (2.25%)	0 / 88 (0.00%)
occurrences (all)	1	2	0
Otitis media			
subjects affected / exposed	1 / 88 (1.14%)	2 / 89 (2.25%)	0 / 88 (0.00%)
occurrences (all)	1	2	0
Pharyngitis			
subjects affected / exposed	1 / 88 (1.14%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	2 / 88 (2.27%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	2	0	0

Varicella			
subjects affected / exposed	2 / 88 (2.27%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences (all)	2	0	1
Acute sinusitis			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Bronchopneumonia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Candidiasis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Croup infectious			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Herpangina			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	1 / 88 (1.14%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 88 (0.00%)	1 / 89 (1.12%)	0 / 88 (0.00%)
occurrences (all)	0	1	0

Viral diarrhoea			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulit			
subjects affected / exposed	0 / 88 (0.00%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypophagia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 89 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	After the Infant Series 7vPnC	Toddler Dose 13vPnC	Toddler Dose 7vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 89 (21.35%)	35 / 84 (41.67%)	41 / 88 (46.59%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 89 (1.12%)	3 / 84 (3.57%)	2 / 88 (2.27%)
occurrences (all)	1	3	2
Injection site erythema			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥ 38 degrees C but ≤ 39 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 89 (0.00%)	7 / 51 (13.73%)	10 / 51 (19.61%)
occurrences (all)	0	7	10
Fever ≥ 38 degrees C but ≤ 39 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever ≥ 38 degrees C but ≤ 39 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Fever > 39 degrees C but ≤ 40 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 89 (0.00%)	1 / 50 (2.00%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Fever > 39 degrees C but ≤ 40 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 89 (0.00%)	13 / 57 (22.81%)	15 / 54 (27.78%)
occurrences (all)	0	13	15
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 89 (0.00%)	18 / 59 (30.51%)	21 / 56 (37.50%)
occurrences (all)	0	18	21
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 89 (0.00%)	11 / 52 (21.15%)	8 / 52 (15.38%)
occurrences (all)	0	11	8
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 89 (0.00%)	11 / 54 (20.37%)	20 / 58 (34.48%)
occurrences (all)	0	11	20
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Atopy			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Perineal fistula			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
Rhinorrhoea			
subjects affected / exposed	2 / 89 (2.25%)	5 / 84 (5.95%)	0 / 88 (0.00%)
occurrences (all)	2	5	0
Cough			
subjects affected / exposed	0 / 89 (0.00%)	2 / 84 (2.38%)	1 / 88 (1.14%)
occurrences (all)	0	2	1
Productive cough			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Grunting			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Upper airway obstruction			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Investigations			
Urine output decreased			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	4 / 89 (4.49%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	4	0	0
Ear and labyrinth disorders			

Middle ear effusion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Entropion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	1 / 88 (1.14%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Intussusception			

subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	4 / 89 (4.49%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	4	0	0
Eczema			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Heat rash			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Rash papular			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Skin erosion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Dermal cyst			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eczema infantile			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 89 (0.00%)	19 / 56 (33.93%)	14 / 54 (25.93%)
occurrences (all)	0	19	14
Tenderness (any); Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Tenderness (significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 89 (0.00%)	3 / 51 (5.88%)	1 / 50 (2.00%)
occurrences (all)	0	3	1
Tenderness (significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Tenderness (significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Swelling (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 89 (0.00%)	11 / 49 (22.45%)	10 / 53 (18.87%)
occurrences (all)	0	11	10
Swelling (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Swelling (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Swelling (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 89 (0.00%)	4 / 49 (8.16%)	7 / 52 (13.46%)
occurrences (all)	0	4	7
Swelling (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Swelling (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Swelling (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 89 (0.00%)	9 / 49 (18.37%)	4 / 51 (7.84%)
occurrences (all)	0	9	4
Swelling (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Swelling (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Swelling (severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 89 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Redness (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 89 (0.00%)	15 / 52 (28.85%)	12 / 54 (22.22%)
occurrences (all)	0	15	12
Redness (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Redness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Redness (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 89 (0.00%)	9 / 51 (17.65%)	10 / 54 (18.52%)
occurrences (all)	0	9	10
Redness (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0

Redness (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Redness (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 89 (0.00%)	8 / 50 (16.00%)	3 / 50 (6.00%)
occurrences (all)	0	8	3
Redness (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Redness (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	4 / 89 (4.49%)	7 / 84 (8.33%)	10 / 88 (11.36%)
occurrences (all)	5	7	10
Bronchiolitis			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 89 (0.00%)	3 / 84 (3.57%)	9 / 88 (10.23%)
occurrences (all)	0	3	10
Bronchitis			

subjects affected / exposed	1 / 89 (1.12%)	1 / 84 (1.19%)	2 / 88 (2.27%)
occurrences (all)	1	1	2
Gastroenteritis			
subjects affected / exposed	0 / 89 (0.00%)	4 / 84 (4.76%)	2 / 88 (2.27%)
occurrences (all)	0	4	2
Otitis media acute			
subjects affected / exposed	1 / 89 (1.12%)	0 / 84 (0.00%)	4 / 88 (4.55%)
occurrences (all)	1	0	4
Pharyngotonsillitis			
subjects affected / exposed	1 / 89 (1.12%)	1 / 84 (1.19%)	3 / 88 (3.41%)
occurrences (all)	1	1	3
Acute tonsillitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	2 / 88 (2.27%)
occurrences (all)	0	1	2
Pneumonia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Varicella			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Croup infectious			

subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	1 / 89 (1.12%)	1 / 84 (1.19%)	2 / 88 (2.27%)
occurrences (all)	1	1	2
Hordeolum			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	1 / 88 (1.14%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 84 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	2 / 88 (2.27%)
occurrences (all)	0	1	2
Laryngitis			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Periorbital cellulit			
subjects affected / exposed	0 / 89 (0.00%)	1 / 84 (1.19%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			

Hypophagia subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	0 / 84 (0.00%) 0	0 / 88 (0.00%) 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:

Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[21] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[25] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[26] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[27] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[28] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[29] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[30] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[31] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[32] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[33] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[34] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[35] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[36] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[37] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[38] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[39] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[40] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[41] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[42] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 January 2009	Amendment 5 was issued approximately 6 months after the study start. It provided for an interim analysis to be conducted after all subjects had completed the infant series. The statistical analysis plan (SAP) was amended at the same time to include the interim analysis. Amendment 5 also permitted rotavirus vaccine to be administered at any time during the study, rather than only during protocol-specified time frames.
13 July 2009	Amendment 6, issued approximately 6 months later, rescinded this provision, because all subjects concerned had already received rotavirus vaccines, which were reported as protocol deviations if they were administered outside of the protocol-specified time frames

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported