Clinical trial results:
A phase 3, randomized, Active-Controlled, Double-blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine in Healhy Infants Given With Routine Pediatric Vaccination in Italy

Summary

EudraCT number	2005-004771-38
Trial protocol	IT
Global end of trial date	21 February 2008

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	02 August 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-500

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00366899
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851096

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 September 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 February 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

-To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local injection site reactions, systemic events, and adverse events (AEs) .
- To demonstrate that the immune response induced by Infanrix hexa given with 13vPnC is noninferior to the immune response induced by Infanrix hexa given with 7vPnC when measured 1 month after the toddler dose. Response to the following antigen in Infanrix hexa was assessed: hepatitis B.
-- To assess the immune response to 13vPnC 1 month after the infant series as measured by serum immunoglobulin G (IgG) responses. To assess the immune response to 13vPnC before the toddler dose as measured by serum IgG responses.

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	26 October 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Italy: 606
Worldwide total number of subjects	606
EEA total number of subjects	606

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)	606

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:

Subjects were recruited in Italy from October 2006 to March 2007.

Pre-assignment

Screening details:

Subjects were enrolled into the study according to inclusion/exclusion criteria without a screening period. One subject was prerandomized and counted twice.

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:

Subjects received 13-valent pneumococcal conjugate vaccine (13vPnC) coadministered with diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and Haemophilus influenzae type b (Hib) vaccine (Infanrix hexa) in infant series. At the start, one subject was counted twice, one subject randomized to 13vPnC, incorrectly received 7vPnC. At vaccine dose 1, two subjects randomized to 13vPnC, incorrectly received 7vPnC. At vaccine dose 2, one subject randomized to 13vPnC, incorrectly received 7vPnC.

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

Dosage and administration details:

Subjects received 0.5-mL dose of DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series.

Investigational medicinal product name	13vPnc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of 13vPnC at 3 and 5 months (infant series).

Arm title	7vPnC Infant Series

Arm description:

Subjects received 7-valent pneumococcal conjugate vaccine (7vPnC) coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series. At the start, one subject randomized to 7vPnC but never vaccinated.

Arm type	Active comparator

Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of DTPa, hepatitis B, inactivated poliovirus, Hib vaccine (Infanrix hexa) in infant series.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of 7vPnC at 3 and 5 months (infant series).

Number of subjects in period 1	13vPnC Infant Series	7vPnC Infant Series
Started	303	303
Vaccinated Dose 1	302	302
Vaccinated Dose 2	296	293
Completed	294	291
Not completed	9	12
Consent withdrawn by subject	4	7
'Protocol Violation '	2	1
'Randomized but not consented '	1	-
Failed to return	1	1
'Adverse Event '	-	1
'Physician Decision '	1	-
Lost to follow-up	-	2

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 Infant Series

Arm description:

Included subjects who received 13vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC After Infant Series

Arm description:

Included subjects who received 7vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC After Infant Series	7vPnC After Infant Series
Started	294	291
Completed	287	282
Not completed	7	9
Consent withdrawn by subject	1	4
'Protocol Violation '	1	-
'Adverse Event '	1	2
Lost to follow-up	4	3

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:

Subjects received 13vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) at 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:

Subjects received one single 0.5 mL dose of 13vPnC at 11 months of age (toddler dose).

Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) at 11 months of age (toddler dose).

Arm title	7vPnC Toddler Dose

Arm description:

Subjects received 7vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) at toddler dose.

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

Dosage and administration details:

Subjects received 0.5 mL dose of DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) at 11 months of age (toddler dose).

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of 7vPnC at 11 months of age (toddler dose).

Number of subjects in period 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	287	282
Completed	285	281
Not completed	2	1
Consent withdrawn by subject	1	1
'Protocol Violation '	1	-

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC Infant Series
Reporting group description:	
Subjects received 13-valent pneumococcal conjugate vaccine (13vPnC) coadministered with diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and Haemophilus influenzae type b (Hib) vaccine (Infanrix hexa) in infant series. At the start, one subject was counted twice, one subject randomized to 13vPnC, incorrectly received 7vPnC. At vaccine dose 1, two subjects randomized to 13vPnC, incorrectly received 7vPnC. At vaccine dose 2, one subject randomized to 13vPnC, incorrectly received 7vPnC.	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Subjects received 7-valent pneumococcal conjugate vaccine (7vPnC) coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series. At the start, one subject randomized to 7vPnC but never vaccinated.	

Reporting group values	13vPnC Infant Series	7vPnC Infant Series	Total
Number of subjects	303	303	606
Age categorical			
Units: Subjects			
Age continuous			
Units: months			
arithmetic mean	2.9	2.9	
standard deviation	± 0.3	± 0.3	-
Gender categorical			
Units: Subjects			
Female	138	133	271
Male	164	170	334
Unknown	1	0	1

End points

End points reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description:	
Subjects received 13-valent pneumococcal conjugate vaccine (13vPnC) coadministered with diphtheria-tetanus-acellular pertussis (DTPa), hepatitis B, inactivated poliovirus, and Haemophilus influenzae type b (Hib) vaccine (Infanrix hexa) in infant series. At the start, one subject was counted twice, one subject randomized to 13vPnC, incorrectly received 7vPnC. At vaccine dose 1, two subjects randomized to 13vPnC, incorrectly received 7vPnC. At vaccine dose 2, one subject randomized to 13vPnC, incorrectly received 7vPnC.	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Subjects received 7-valent pneumococcal conjugate vaccine (7vPnC) coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series. At the start, one subject randomized to 7vPnC but never vaccinated.	
Reporting group title	13vPnC After Infant Series
Reporting group description:	
Included subjects who received 13vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series.	
Reporting group title	7vPnC After Infant Series
Reporting group description:	
Included subjects who received 7vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) in infant series.	
Reporting group title	13vPnC Toddler Dose
Reporting group description:	
Subjects received 13vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) at toddler dose.	
Reporting group title	7vPnC Toddler Dose
Reporting group description:	
Subjects received 7vPnC coadministered with DTPa, hepatitis B, inactivated poliovirus, and Hib vaccine (Infanrix hexa) at toddler dose.	
Subject analysis set title	13vPnC Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 3 months of age.	
Subject analysis set title	7vPnC Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at 3 months of age.	
Subject analysis set title	13vPnC Toddler Dose
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 11 months of age.	
Subject analysis set title	7vPnC Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at 5 months of ag e.	
Subject analysis set title	13vPnC Dose 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 5 months of age.

Subject analysis set title	7vPnC Toddler Dose
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at 11 months of age.

Subject analysis set title	7vPnC After 2-Dose Infant Series
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at 3 and 5 months of age (infant series).

Subject analysis set title	13vPnC After 2-Dose Infant Series
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 3 and 5 months of age (infant series).

Subject analysis set title	7vPnC After Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at 11 months of age (toddler dose).

Subject analysis set title	13vPnC After Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 11 months of age (toddler dose).

Subject analysis set title	13vPnC Before Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 11 months of age (toddler dose).

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions

End point title	Percentage of Subjects Reporting Pre-Specified Local

End point description:

Local reactions were collected 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 (more than [>]7.0 cm). Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine, (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary

End point timeframe:

During the 4-day period after each dose

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	7vPnC Dose 1	13vPnC Dose 1	13vPnC Toddler Dose	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	255	243	204	226
Units: Percentage of Subjects				
number (not applicable)				
Tenderness - Any (n=234,243,214,215,199,188)	30	32.1	47.2	36.7
Tenderness-Significant (n=224,231,199,199,164,153)	3.5	2.7	8.5	5
Swelling - Any (n=232,240,207,209,175,165)	19.6	19	28.6	28.7
Swelling - Mild (n=232,240,207,208,174,161)	18.3	17.7	26.4	26.4
Swelling - Moderate (n=223,229,198,195,160,157)	3.1	3.6	7.5	5.1
Swelling - Severe (n=222,229,197,194,159,152)	0	0	0	0
Redness - Any (n=233,245,213,212,178,174)	26.5	25.8	36.5	34.4
Redness - Mild (n=233,244,211,211,178,172)	24.6	24	32.6	32.2
Redness - Moderate (n=222,231,200,195,160,156)	3	2.7	7.5	3.6
Redness - Severe (n=222,229,197,194,159,152)	0	0	0	0

End point values	13vPnC Dose 2	7vPnC Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	225	200		
Units: Percentage of Subjects				
number (not applicable)				
Tenderness - Any (n=234,243,214,215,199,188)	30.4	44.1		
Tenderness-Significant (n=224,231,199,199,164,153)	4.5	5.9		
Swelling - Any (n=232,240,207,209,175,165)	24.6	27.3		
Swelling - Mild (n=232,240,207,208,174,161)	21.7	21.7		
Swelling - Moderate (n=223,229,198,195,160,157)	5.6	10.2		
Swelling - Severe (n=222,229,197,194,159,152)	0	0		
Redness - Any (n=233,245,213,212,178,174)	31.5	36.2		
Redness - Mild (n=233,244,211,211,178,172)	28.4	30.8		
Redness - Moderate (n=222,231,200,195,160,156)	5.5	10.9		
Redness - Severe (n=222,229,197,194,159,152)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events[2]

End point description:

Systemic events (fever greater than or equal to [≥]37.5 degrees Celsius [C], fever ≥38 C but less than or equal to [≤]39 C, fever greater than [>]39 C but ≤40 C, fever >40 C, decreased appetite, irritability, increased sleep, decreased sleep, hives, use of medication (meds) to treat symptoms, and use of medication to prevent symptoms) were reported using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine, (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary

End point timeframe:

During the 4-day period after each dose

Notes:

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

End point values	7vPnC Dose 1	13vPnC Dose 1	13vPnC Toddler Dose	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	286	291	245	260
Units: Percentage of Subjects				
number (not applicable)				
Fever ≥38°C but ≤39°C (n=247,246,227,226,204,197)	38.6	41.7	63.7	60.6
Fever >39°C but ≤40°C (n=224,233,204,201,167,160)	4.7	3.6	9.6	7
Fever >40°C (n=222,230,198,195,160,152)	0	0	0	0
Decreased appetite (n=246,248,220,218,198,197)	34.3	35.4	52	45.4
Irritability (n=258,259,245,243,221,227)	63.7	72.9	74.7	75.3
Increased sleep (n=269,276,226,232,195,196)	64.5	65.8	53.8	56.5
Decreased sleep (n=244,242,222,213,180,171)	36.4	39.3	35.6	41.8
Meds-treat symptoms (n=244,245,219,228,192,190)	30.6	34.8	53.1	47.8
Meds-prevent symptoms (n=230,238,208,208,172,169)	18.1	12.6	27.9	24.5

End point values	13vPnC Dose 2	7vPnC Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	269	249		
Units: Percentage of Subjects				
number (not applicable)				
Fever ≥38°C but ≤39°C (n=247,246,227,226,204,197)	55.5	52.3		

Fever >39°C but ≤40°C (n=224,233,204,201,167,160)	6.9	12.5		
Fever >40°C (n=222,230,198,195,160,152)	0	0.7		
Decreased appetite (n=246,248,220,218,198,197)	47.3	57.4		
Irritability (n=258,259,245,243,221,227)	75.5	74.9		
Increased sleep (n=269,276,226,232,195,196)	57.1	54.6		
Decreased sleep (n=244,242,222,213,180,171)	40.1	35.7		
Meds-treat symptoms (n=244,245,219,228,192,190)	43.4	43.7		
Meds-prevent symptoms (n=230,238,208,208,172,169)	20.2	24.3		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving Predefined Antibody Levels for Concomitant Antigen Pertussis, Hepatitis B, Haemophilus influenzae Type b, Diphtheria, Tetanus and Polio After the 2-Dose Infant Series and After the Toddler Dose

End point title	Percentage of Subjects Achieving Predefined Antibody Levels for Concomitant Antigen Pertussis, Hepatitis B, Haemophilus influenzae Type b, Diphtheria, Tetanus and Polio After the 2-Dose Infant Series and After the Toddler Dose

End point description:

Percentage of Subjects achieving predefined antibody threshold levels for Pertussis Toxoid (PT) ≥5 enzyme-linked immunosorbent assay (ELISA) units per milliliter (EU/mL), Filamentous Haemagglutinin (FHA) ≥5 or ≥7.82 EU/mL, and Pertactin (PRN) ≥5 EU/mL, ≥10.0 Milli-International Units Per Milliliter (mIU/mL) for Hepatitis B, Hib 0.15 microgram (µg)/mL, 0.01 or 0.1 IU/mL for Diphtheria, 0.1 IU/mL for Tetanus, and ≥1:8 titer for Polio (Type 1, 2, and 3) with the corresponding 95 percent (%) confidence interval (CI) for antigens are presented. Evaluable immunogenicity (per protocol) population who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n) = number of subjects with a determinate postinfant antibody concentration/titer for the given concomitant antigen.

End point type	Primary

End point timeframe:

One month after the infant series (6 months of age) and after the toddler dose (12 months of age)

End point values	13vPnC After 2-Dose Infant Series	7vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	275	279	254	261
Units: percentage of subjects				
number (confidence interval 95%)				
Pertussis, PT ≥5 EU/mL (n=250,272,235,219)	99.6 (97.8 to 100)	100 (98.7 to 100)	100 (98.4 to 100)	100 (98.1 to 100)
Pertussis, FHA ≥5 EU/mL (n=243,272,229,214)	100 (98.5 to 100)	100 (98.7 to 100)	100 (98.4 to 100)	100 (86.9 to 97.7)

Pertussis, FHA ≥7.82 EU/mL (n=243,272,229,214)	100 (98.5 to 100)	100 (98.7 to 100)	100 (98.4 to 100)	100 (98 to 100)
Pertactin ≥5 EU/mL (n=248,270,234,217)	100 (98.5 to 100)	100 (98.6 to 100)	100 (98.4 to 100)	100 (97.9 to 100)
Hepatitis B ≥ 10.0 mIU/mL	93.8 (90.2 to 96.3)	93.1 (89.5 to 95.8)	98.4 (96 to 99.6)	98.8 (97.9 to 100)
Haemophilus influenzae type b 0.15 µg/mL	87 (82 to 91.1)	90.3 (86.1 to 93.5)	99.6 (97.7 to 100)	98.2 (91.8 to 97.8)
Haemophilus influenzae type b 1.0 µg/mL	49.4 (42.7 to 56)	48.7 (42.6 to 54.9)	96.2 (92.9 to 98.2)	92.2 (91.6 to 97.7)
Diptheria 0.01 IU/mL (n=207,240,164,190)	100 (98.2 to 100)	100 (98.5 to 100)	100 (97.8 to 100)	100 (91.7 to 97.8)
Diptheria 0.1 IU/mL (n=207,240,164,190)	92.8 (88.3 to 95.9)	96.3 (93 to 98.3)	100 (97.8 to 100)	100 (98.1 to 100)
Tetanus 0.1 IU/mL (n=155,214,125,96)	94.2 (89.3 to 97.3)	92.5 (88.1 to 95.7)	97.6 (93.1 to 99.5)	93.8 (98.3 to 100)
Polio, Type 1 ≥1:8	99.5 (97.3 to 100)	99.6 (97.9 to 100)	100 (97.7 to 100)	100 (98.3 to 100)
Polio, Type 2 ≥1:8	95.6 (91.8 to 98)	96.6 (93.6 to 98.4)	100 (97.6 to 100)	100 (98.3 to 100)
Polio, Type 3 ≥1:8	99.5 (97.3 to 100)	98.9 (96.7 to 99.8)	100 (97.6 to 100)	100 (96.6 to 99.8)
Pertussis, PT (infant ≥16; Toddler ≥21) EU/mL	95.2 (91.8 to 97.5)	95.2 (92 to 97.4)	92.8 (88.7 to 95.7)	95.4 (95.4 to 99.5)
Pertussis, FHA (Infant ≥31; Toddler ≥162) EU/mL	94.7 (91 to 97.1)	95.6 (92.4 to 97.7)	95.2 (91.6 to 97.6)	95.3 (87.8 to 95.4)
Pertactin (Infant ≥40; Toddler ≥106) EU/mL	91.9 (87.8 to 95)	95.2 (91.9 to 97.4)	94.9 (91.2 to 97.3)	95.4 (98.1 to 100)

Statistical analyses

Statistical analysis title	Pertussis PT ≥5 EU/mL

Statistical analysis description:

For Pertussis PT the difference in percentages between the two groups (13vPnC – 7vPnC) at ≥5 EU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	1

Notes:

[3] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis PT ≥16 EU/mL

Statistical analysis description:

For Pertussis PT the difference in percentages between the two groups (13vPnC – 7vPnC) at ≥16 EU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	3.8

Notes:

[4] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis FHA ≥5 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥5 EU/mL threshold was calculated.

Comparison groups	7vPnC After 2-Dose Infant Series v 13vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.4

Notes:

[5] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis FHA ≥7.82 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentages between the two groups (13vPnC – 7vPnC) at ≥7.82 EU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.4

Notes:

[6] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis FHA ≥31 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥31 EU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	2.9

Notes:

[7] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertactin ≥5 EU/mL

Statistical analysis description:

For Pertactin the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥5 EU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	1.4

Notes:

[8] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertactin ≥40 EU/mL

Statistical analysis description:

For Pertactin the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥40 EU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series

Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Difference
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.8
upper limit	1

Notes:

[9] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Hepatitis B ≥ 10.0 mIU/mL

Statistical analysis description:

For hepatitis B the difference in percentages between the two groups (13vPnC – 7vPnC) at ≥10.0 mIU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Parameter estimate	Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	5

Notes:

[10] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Haemophilus influenzae type b at 0.15 µg/mL

Statistical analysis description:

For Haemophilus influenzae type b the difference in percentages between the two groups (13vPnC – 7vPnC) at 0.15 µg/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	Difference
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	2.4

Notes:

[11] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Haemophilus influenzae type b at 1.0 µg/mL

Statistical analysis description:

For Haemophilus influenzae type b the difference in percentages between the two groups (13vPnC – 7vPnC) at 1.0 µg/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
Parameter estimate	Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.2
upper limit	9.5

Notes:

[12] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Diptheria at 0.01 IU/mL

Statistical analysis description:

For Diptheria the difference in percentages between the two groups (13vPnC – 7vPnC) at 0.01 IU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	1.6

Notes:

[13] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Diptheria at 0.1 IU/mL

Statistical analysis description:

For Diptheria the difference in percentage between the two groups (13vPnC – 7vPnC) at 0.1 IU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
Parameter estimate	Difference
Point estimate	-3.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	0.8

Notes:

[14] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Tetanus at 0.1 IU/mL

Statistical analysis description:

For Tetanus the difference in percentage between the two groups (13vPnC – 7vPnC) at 0.1 IU/mL threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
Parameter estimate	Difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	7.1

Notes:

[15] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Polio, Type 1 ≥1:8

Statistical analysis description:

For Polio Type 1 the difference in percentage between the two groups (13vPnC – 7vPnC) at ≥1:8 threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[16]
Parameter estimate	Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.7

Notes:

[16] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Polio, Type 2 ≥1:8

Statistical analysis description:

For Polio Type 2 the difference in percentage between the two groups (13vPnC – 7vPnC) at ≥1:8 threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series

Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[17]
Parameter estimate	Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	2.8

Notes:

[17] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Polio, Type 3 ≥1:8

Statistical analysis description:

For Polio Type 3 the difference in percentages between the two groups (13vPnC – 7vPnC) at ≥1:8 threshold was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
Parameter estimate	Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	2.9

Notes:

[18] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis, PT ≥5 EU/mL

Statistical analysis description:

For Pertussis PT the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥5 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.7

Notes:

[19] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis FHA at ≥5 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥5 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.7

Notes:

[20] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis PT ≥21 EU/mL

Statistical analysis description:

For Pertussis PT the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥21 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[21]
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.3
upper limit	1.8

Notes:

[21] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis FHA at ≥7.82 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥7.82 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[22]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.7

Notes:

[22] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertussis FHA ≥162 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥162 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[23]
Parameter estimate	Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	4.1

Notes:

[23] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertactin ≥5 EU/mL

Statistical analysis description:

For Pertactin the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥5 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[24]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.7

Notes:

[24] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Pertactin ≥106 EU/mL

Statistical analysis description:

For Pertactin the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥106 EU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[25]
Parameter estimate	Difference
Point estimate	-0.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.7
upper limit	3.7

Notes:

[25] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Hepatitis B ≥10.0 mIU/mL

Statistical analysis description:

For hepatitis B the difference in percentages between the two groups (13vPnC - 7vPnC) at ≥10.0 mIU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[26]
Parameter estimate	Difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	2

Notes:

[26] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Haemophilus influenzae type b at 0.15 µg/mL

Statistical analysis description:

For Haemophilus influenzae type b the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.15 µg/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[27]
Parameter estimate	Difference
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	4.2

Notes:

[27] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Haemophilus influenzae type b at 1.0 µg/mL

Statistical analysis description:

For Haemophilus influenzae type b the difference in percentage between the two groups (13vPnC - 7vPnC) at 1.0 µg/mL threshold was calculated.

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

Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[28]
Parameter estimate	Difference
Point estimate	4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	8.7

Notes:

[28] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Diphtheria at 0.1 IU/mL

Statistical analysis description:

For Diphtheria the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.1 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2

Notes:

[29] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Diphtheria at 0.01 IU/mL

Statistical analysis description:

For Diphtheria the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[30]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2

Notes:

[30] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Tetanus at 0.1 IU/mL

Statistical analysis description:

For Tetanus the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.1 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[31]
Parameter estimate	Difference
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	10.9

Notes:

[31] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Polio, Type 1 ≥1:8

Statistical analysis description:

For Polio Type 1 the difference in percentage between the two groups (13vPnC - 7vPnC) at ≥1:8 threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[32]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.1

Notes:

[32] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Polio, Type 2 ≥1:8

Statistical analysis description:

For Polio Type 2 the difference in percentage between the two groups (13vPnC - 7vPnC) at ≥1:8 threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[33]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.1

Notes:

[33] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Statistical analysis title	Polio, Type 3 ≥1:8

Statistical analysis description:

For Polio Type 3 the difference in percentage between the two groups (13vPnC - 7vPnC) at ≥1:8 threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[34]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.1

Notes:

[34] - Non-inferiority for concomitant antigens was declared if the lowest limit of the 2-sided 95% CI for the difference between the two groups was > -10%.

Primary: Geometric Mean Antibody Concentration (GMC) of Pertussis in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) of Pertussis in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point description:

GMC of Pertussis (PT, FHA, PRN) were measured using an anti-Bordetella pertussis ELISA. Results were recorded in ELISA units per milliliter (EU/mL). Evaluable immunogenicity (per protocol) population adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (6 months of age) and after the toddler dose (12 months of age)

End point values	13vPnC After 2-Dose Infant Series	7vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	275	279	254	261
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis FHA	102.87 (149.54 to 188.18)	105.17 (97.25 to 113.73)	463.23 (425.19 to 504.67)	456.55 (415.06 to 502.18)
Pertussis PT	50.01 (94.35 to 112.16)	48.44 (44.71 to 52.49)	60.89 (55.61 to 66.67)	64.53 (59.13 to 70.42)
Pertussis PRN	167.76 (45.82 to 54.58)	166.19 (150.28 to 183.78)	339.3 (309.16 to 372.38)	361.7 (328.59 to 398.14)

Statistical analyses

Statistical analysis title	Pertussis PRN: After 2-Dose Infant Series
Statistical analysis description:	
For Pertussis PRN the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[35]
Parameter estimate	Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.17

Notes:

[35] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Pertussis PT: After 2-Dose Infant Series
Statistical analysis description:	
For Pertussis PT the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[36]
Parameter estimate	Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.16

Notes:

[36] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Pertussis FHA: After 2-Dose Infant Series
Statistical analysis description:	
For Pertussis FHA the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series

Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[37]
Parameter estimate	Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.1

Notes:

[37] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Pertussis PRN: After Toddler dose

Statistical analysis description:

For Pertussis PRN the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[38]
Parameter estimate	Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.07

Notes:

[38] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Pertussis PT: After Toddler dose

Statistical analysis description:

For Pertussis PT the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[39]
Parameter estimate	Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.07

Notes:

[39] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Pertussis FHA: After Toddler dose

Statistical analysis description:

For Pertussis FHA the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[40]
Parameter estimate	Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.15

Notes:

[40] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Geometric Mean Antibody Concentration (GMC) for Hepatitis B in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) for Hepatitis B in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After Toddler Dose

End point description:

GMC of anti-hepatitis B surface antigen (HBsAg) using an Food and Drug Administration (FDA) approved in vitro diagnostic kit. Evaluable immunogenicity (per protocol) population had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

One month after the infant series (6 months of age) and the toddler dose (12 months of age)

End point values	13vPnC After 2-Dose Infant Series	7vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	273	276	252	255
Units: mIU/mL				
geometric mean (confidence interval 95%)	260.46 (214.47 to 316.31)	272.67 (220.83 to 336.68)	1655.3 (1343.3 to 2039.77)	2284.95 (1878.82 to 2778.88)

Statistical analyses

Statistical analysis title	Hepatitis b: After 2-Dose Infant Series

Statistical analysis description:

For Hepatitis b the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series

Number of subjects included in analysis	549
Analysis specification	Pre-specified
Analysis type	non-inferiority[41]
Parameter estimate	Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.27

Notes:

[41] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the geometric mean concentration (GMC)/geometric mean titer (GMT) ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Hepatitis b: After Toddler dose

Statistical analysis description:

For Hepatitis b the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	non-inferiority[42]
Parameter estimate	Ratio
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.96

Notes:

[42] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Geometric Mean Antibody Concentration (GMC) of Haemophilus influenzae Type b (Hib) in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) of Haemophilus influenzae Type b (Hib) in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point description:

GMC for Hib polyribosylribitol phosphate as measured by ELISA, expressed in µg/mL. Evaluable immunogenicity (per protocol) population had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (6 months of age) and after the toddler dose (12 months of age)

End point values	13vPnC After 2-Dose Infant Series	7vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	231	267	235	218
Units: µg/mL				
geometric mean (confidence interval 95%)	0.99 (0.8 to 1.21)	1 (0.83 to 1.2)	9.09 (7.8 to 10.6)	8.85 (7.37 to 10.62)

Statistical analyses

Statistical analysis title	Haemophilus influenzae b:After 2Dose Infant Series
Statistical analysis description:	
For Haemophilus influenzae type b the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	non-inferiority[43]
Parameter estimate	Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.3

Notes:

[43] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Haemophilus influenzae b: After Toddler dose
Statistical analysis description:	
For Haemophilus influenzae type b the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	453
Analysis specification	Pre-specified
Analysis type	non-inferiority[44]
Parameter estimate	Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.3

Notes:

[44] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Geometric Mean Antibody Concentration (GMC) of Diptheria and Tetanus in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) of Diptheria

	and Tetanus in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point description:

GMC of anti-diphtheria and anti-tetanus toxoids as measured by ELISA (IU/mL). Evaluable immunogenicity (per protocol) population had valid and determinate assay results, and had no other major protocol violations; (n) = number of subjects with a determinate antibody concentration/titer for the specified concomitant antigen.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (6 months of age) and after the toddler dose (12 months of age)

End point values	13vPnC After 2-Dose Infant Series	7vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	275	279	254	261
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diptheria (n=207,240,164,190)	0.52 (0.46 to 0.6)	0.67 (0.59 to 0.76)	2.77 (2.45 to 3.13)	3.71 (3.28 to 4.2)
Tetanus (n=155,214,125,96)	0.53 (0.45 to 0.63)	0.63 (0.53 to 0.74)	2.62 (2.12 to 3.25)	2.09 (1.56 to 2.81)

Statistical analyses

Statistical analysis title	Diphtheria toxoid: After 2-Dose Infant Series

Statistical analysis description:

For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[45]
Parameter estimate	Ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.94

Notes:

[45] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Diphtheria toxoid: After Toddler dose

Statistical analysis description:

For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated.

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

Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[46]
Parameter estimate	Ratio
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.89

Notes:

[46] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Tetanus: After Toddler dose

Statistical analysis description:

For Tetanus the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[47]
Parameter estimate	Ratio
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.79

Notes:

[47] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Tetanus: After 2-Dose Infant Series

Statistical analysis description:

For Tetanus the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[48]
Parameter estimate	Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.08

Notes:

[48] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Geometric Mean Antibody Concentration (GMC) of Polio Types 1, 2, and 3 in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and

After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) of Polio Types 1, 2, and 3 in the 13vPnC Group Relative to the 7vPnC Group After the 2-Dose Infant Series and After the Toddler Dose

End point description:

GMC of Polio as measured using a polio in vitro plaque neutralization. Evaluable immunogenicity (per protocol) population had valid and determinate assay results, and had no other major protocol violations; (n) = number of subjects with a determinate antibody concentration/titer for the specified concomitant antigen.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (6 months of age) and after the toddler dose (12 months of age)

End point values	13vPnC After 2-Dose Infant Series	7vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	275	279	254	261
Units: Titers				
geometric mean (confidence interval 95%)				
Polio Type 1 (n=207,262,156,179)	180.72 (154.31 to 211.64)	207.17 (178.64 to 240.25)	924.52 (782.71 to 1092.03)	1348.04 (1163.56 to 1561.77)
Polio Type 2 (n=205,262,153,175)	123.74 (102.68 to 149.13)	130.39 (382.57 to 534.35)	1141.62 (958.68 to 1359.47)	1340.51 (1147.88 to 1565.48)
Polio Type 3 (n=205,262,153,178)	397.32 (327 to 482.76)	452.14 (109.96 to 154.63)	1567.64 (1289.72 to 1905.45)	2421.31 (2072.82 to 2828.39)

Statistical analyses

Statistical analysis title	Polio Type 1: After 2-Dose Infant Series

Statistical analysis description:

For Polio Type 1 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[49]
Parameter estimate	Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.08

Notes:

[49] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Polio Type 2: After 2-Dose Infant Series

Statistical analysis description:

For Polio Type 2 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[50]
Parameter estimate	Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.22

Notes:

[50] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Polio Type 3: After 2-Dose Infant Series

Statistical analysis description:

For Polio Type 3 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After 2-Dose Infant Series v 7vPnC After 2-Dose Infant Series
Number of subjects included in analysis	554
Analysis specification	Pre-specified
Analysis type	non-inferiority[51]
Parameter estimate	Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.13

Notes:

[51] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Polio Type 1: After Toddler dose

Statistical analysis description:

For Polio Type 1 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[52]
Parameter estimate	Ratio
Point estimate	0.69

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.86

Notes:

[52] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Polio Type 2: After Toddler dose

Statistical analysis description:

For Polio Type 2 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[53]
Parameter estimate	Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.07

Notes:

[53] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	Polio Type 3: After Toddler dose

Statistical analysis description:

For Polio Type 3 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	515
Analysis specification	Pre-specified
Analysis type	non-inferiority[54]
Parameter estimate	Ratio
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.83

Notes:

[54] - Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC/GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Primary: Percentage of Subjects Achieving an Antibody Level of ≥0.35 µg/mL in the 13vPnC Group After the 2-Dose Infant Series and Before the Toddler Dose

End point title	Percentage of Subjects Achieving an Antibody Level of ≥0.35 µg/mL in the 13vPnC Group After the 2-Dose Infant Series and Before the Toddler Dose[55]

End point description:

Percentages of Subjects achieving World Health Organization (WHO) predefined antibody threshold ≥0.35 µg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to

(serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. The evaluable pneumococcal immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (6 months of age) and before the toddler dose (11 months of age)

Notes:

[55] - 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 After 2-Dose Infant Series	13vPnC Before Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	265	246		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4	96.6 (93.6 to 98.4)	66.9 (60.6 to 72.9)		
Common Serotypes - Serotype 6B	58.4 (52.2 to 64.4)	76.3 (70.3 to 81.6)		
Common Serotypes - Serotype 9V	94.7 (91.2 to 97.1)	70.5 (64.2 to 76.2)		
Common Serotypes - Serotype 14	94.2 (90.6 to 96.7)	94.4 (90.6 to 97)		
Common Serotypes - Serotype 18C	92.4 (88.5 to 95.3)	53 (46.4 to 59.5)		
Common Serotypes - Serotype 19F	95.1 (91.7 to 97.3)	92.4 (88.2 to 95.4)		
Common Serotypes - Serotype 23F	68.6 (62.6 to 74.1)	32.3 (26.4 to 38.7)		
Additional Serotypes - Serotype 1	96.6 (93.6 to 98.4)	83.4 (78 to 87.9)		
Additional Serotypes - Serotype 3	92.8 (89 to 95.6)	30.8 (24.9 to 37.1)		
Additional Serotypes - Serotype 5	91.6 (87.5 to 94.6)	87.3 (82.4 to 91.3)		
Additional Serotypes - Serotype 6A	86.5 (81.8 to 90.4)	86.4 (81.4 to 90.5)		
Additional Serotypes - Serotype 7F	98.5 (96.2 to 99.6)	90.7 (86.3 to 94.1)		
Additional Serotypes - Serotype 19A	98.5 (96.1 to 99.6)	96.2 (92.9 to 98.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in 13vPnC Group After the 2-Dose Infant Series and Before Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in 13vPnC Group After the 2-Dose Infant Series and Before Toddler Dose[56]

End point description:

Antibody GMC for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable pneumococcal immunogenicity (per protocol) population had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (6 months of age) and before the toddler dose (11 months of age)

Notes:

[56] - 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 After 2-Dose Infant Series	13vPnC Before Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	265	246		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4	2.38 (2.11 to 2.67)	0.53 (0.48 to 0.59)		
Common Serotypes - Serotype 6B	0.41 (0.36 to 0.47)	0.61 (0.54 to 0.69)		
Common Serotypes - Serotype 9V	1.68 (1.51 to 1.86)	0.48 (0.43 to 0.52)		
Common Serotypes - Serotype 14	2.84 (2.44 to 3.31)	2.03 (1.79 to 2.3)		
Common Serotypes - Serotype 18C	1.72 (1.54 to 1.93)	0.35 (0.32 to 0.39)		
Common Serotypes - Serotype 19F	3.42 (2.95 to 3.97)	0.94 (0.83 to 1.06)		
Common Serotypes - Serotype 23F	0.61 (0.53 to 0.71)	0.26 (0.23 to 0.29)		
Additional Serotypes - Serotype 1	2.3 (2.03 to 2.6)	0.68 (0.61 to 0.75)		
Additional Serotypes - Serotype 3	1.15 (1.04 to 1.28)	0.25 (0.22 to 0.27)		
Additional Serotypes - Serotype 5	1.27 (1.14 to 1.41)	0.88 (0.8 to 0.97)		
Additional Serotypes - Serotype 6A	1.17 (1.02 to 1.33)	0.81 (0.72 to 0.92)		
Additional Serotypes - Serotype 7F	2.06 (1.88 to 2.26)	0.76 (0.7 to 0.82)		
Additional Serotypes - Serotype 19A	2.87 (2.55 to 3.24)	1.2 (1.06 to 1.35)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving an Antibody Level of ≥0.35 µg/mL in the 13vPnC Relative to the 7vPnC Group After the Toddler Dose

End point title	Percentage of Subjects Achieving an Antibody Level of ≥0.35

	µg/mL in the 13vPnC Relative to the 7vPnC Group After the Toddler Dose

End point description:

Percentages of Subjects achieving WHO predefined antibody threshold ≥0.35 µg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable pneumococcal immunogenicity (per protocol) population had valid and determinate assay results, and had no other major protocol violations; (n) = number of subjects with a determinate IgG antibody concentration to the given serotype.

End point type	Secondary

End point timeframe:

One month after the toddler dose (12 months of age)

End point values	13vPnC After Toddler Dose	7vPnC After Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	249		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=244,245)	100 (98.5 to 100)	100 (98.5 to 100)		
Common Serotypes - Serotype 6B (n=243,243)	100 (98.5 to 100)	100 (98.5 to 100)		
Common Serotypes - Serotype 9V (n=235,248)	100 (98.4 to 100)	100 (98.5 to 100)		
Common Serotypes - Serotype 14 (n=237,240)	99.6 (97.7 to 100)	99.6 (97.7 to 100)		
Common Serotypes - Serotype 18C (n=245,247)	99.2 (97.1 to 99.9)	99.6 (97.8 to 100)		
Common Serotypes - Serotype 19F (n=243,245)	98.8 (96.4 to 99.7)	98.4 (95.9 to 99.6)		
Common Serotypes - Serotype 23F (n=240,243)	99.2 (97 to 99.9)	98.8 (96.4 to 99.7)		
Additional Serotypes - Serotype 1 (n=244,240)	99.6 (97.7 to 100)	3.3 (1.4 to 6.5)		
Additional Serotypes - Serotype 3 (n=245,240)	93.9 (90.1 to 96.5)	6.7 (3.9 to 10.6)		
Additional Serotypes - Serotype 5 (n=245,218)	100 (98.5 to 100)	70.2 (63.6 to 76.2)		
Additional Serotypes - Serotype 6A (n=243,243)	99.6 (97.7 to 100)	86.4 (81.5 to 90.5)		
Additional Serotypes - Serotype 7F (n=242,243)	99.6 (97.7 to 100)	4.9 (2.6 to 8.5)		
Additional Serotypes - Serotype 19A (n=241,241)	100 (98.5 to 100)	99.6 (97.7 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in 13vPnC Relative to 7vPnC Group After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in 13vPnC Relative to 7vPnC Group After the Toddler Dose

End point description:

Antibody GMC for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable pneumococcal immunogenicity (per protocol) had valid and determinate assay results, and had no other major protocol violations; (n) = number of subjects with a determinate antibody concentration for the specified serotype.

End point type	Secondary

End point timeframe:

One month after toddler dose (12 months of age)

End point values	13vPnC After Toddler Dose	7vPnC After Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	249		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=244,245)	4.77 (4.29 to 5.3)	7.08 (6.41 to 7.83)		
Common Serotypes - Serotype 6B (n=243,243)	10 (8.79 to 11.38)	10.39 (9.14 to 11.82)		
Common Serotypes - Serotype 9V (n=235,248)	3.02 (2.74 to 3.32)	4.1 (3.72 to 4.51)		
Common Serotypes - Serotype 14 (n=237,240)	10.3 (9.26 to 11.47)	11.99 (10.77 to 13.35)		
Common Serotypes - Serotype 18C (n=245,247)	2.83 (2.55 to 3.14)	4.26 (3.85 to 4.7)		
Common Serotypes - Serotype 19F (n=243,245)	9.01 (7.84 to 10.36)	8.06 (7.06 to 9.21)		
Common Serotypes - Serotype 23F (n=240,243)	3.43 (3.02 to 3.88)	4.87 (4.3 to 5.51)		
Additional Serotypes - Serotype 1 (n=244,240)	5.76 (5.12 to 6.47)	0.03 (0.03 to 0.04)		
Additional Serotypes - Serotype 3 (n=245,240)	1.22 (1.09 to 1.35)	0.07 (0.06 to 0.08)		
Additional Serotypes - Serotype 5 (n=245,218)	3.59 (3.25 to 3.96)	0.56 (0.49 to 0.64)		
Additional Serotypes - Serotype 6A (n=243,243)	6.78 (6.04 to 7.61)	1.42 (1.21 to 1.66)		
Additional Serotypes - Serotype 7F (n=242,243)	4.31 (3.94 to 4.72)	0.04 (0.04 to 0.05)		
Additional Serotypes - Serotype 19A (n=241,241)	9.81 (8.82 to 10.92)	4.24 (3.85 to 4.67)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Achieving Antibody Titer (OPA) ≥1:8 in 13vPnC Group After the 2-Dose Infant Series and the Toddler Dose

End point title	Percentage of Subjects Achieving Antibody Titer (OPA) ≥1:8 in 13vPnC Group After the 2-Dose Infant Series and the Toddler Dose

End point description:

Percentage of subjects achieving functional antibody titer ≥1:8 as measured by opsonophagocytic activity assay (OPA) along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented (This is not a geometric mean comparison as suggested by the table row heading). OPAs were done in a subset of approximately 100 subjects (range 90-100 per serotype) in the 13vPnC group.

End point type	Other pre-specified

End point timeframe:

One month after infant series dose 2 and after the toddler dose

End point values	13vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	100	100		
Units: % Achieving OPA Titer ≥1:8				
number (confidence interval 95%)				
Common Serotypes - Serotype 4	100 (96.3 to 100)	100 (95.8 to 100)		
Common Serotypes - Serotype 6B	90 (82.4 to 95.1)	99 (94.3 to 100)		
Common Serotypes - Serotype 9V	100 (96.3 to 100)	100 (96.1 to 100)		
Common Serotypes - Serotype 14	100 (96.3 to 100)	100 (96.2 to 100)		
Common Serotypes - Serotype 18C	97 (91.4 to 99.4)	100 (96.3 to 100)		
Common Serotypes - Serotype 19F	96 (90.1 to 98.9)	97.9 (92.7 to 99.7)		
Common Serotypes - Serotype 23F	97 (91.4 to 99.4)	100 (96.3 to 100)		
Additional Serotypes - Serotype 1	94.8 (88.3 to 98.3)	100 (96.2 to 100)		
Additional Serotypes - Serotype 3	99 (94.6 to 100)	100 (96.2 to 100)		
Additional Serotypes - Serotype 5	96 (90 to 98.9)	100 (96.1 to 100)		
Additional Serotypes - Serotype 6A	95.9 (89.9 to 98.9)	100 (96.2 to 100)		
Additional Serotypes - Serotype 7F	100 (96.4 to 100)	100 (96.2 to 100)		
Additional Serotypes - Serotype 19A	95.6 (89 to 98.8)	100 (96 to 100)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Antibody Titer (OPA) in 13vPnC Group After

the 2-Dose Infant Series and the Toddler Dose	
End point title	Geometric Mean Antibody Titer (OPA) in 13vPnC Group After the 2-Dose Infant Series and the Toddler Dose

End point description:

Antibody functionality/geometric mean titer (GMT) as measured by opsonophagocytic activity assay (OPA) 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. OPAs were done in a subset of approximately 100 subjects (range 90-100 per serotype) in the 13vPnC group.

End point type	Other pre-specified

End point timeframe:

One month after infant series dose 2 and after the toddler dose

End point values	13vPnC After 2-Dose Infant Series	13vPnC After Toddler Dose		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	100	100		
Units: Titers				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4	526.69 (431.88 to 642.32)	1276.21 (1025.09 to 1588.85)		
Common Serotypes - Serotype 6B	191.34 (133.35 to 274.55)	2383.31 (1850.47 to 3069.57)		
Common Serotypes - Serotype 9V	3585.8 (2787.34 to 4612.99)	16384 (13066.97 to 20543.06)		
Common Serotypes - Serotype 14	1882.96 (1446.51 to 2451.1)	1903.89 (1580.9 to 2292.88)		
Common Serotypes - Serotype 18C	294.48 (221.8 to 390.98)	1324.41 (1063.57 to 1649.22)		
Common Serotypes - Serotype 19F	222.86 (170.46 to 291.37)	391.97 (296.34 to 518.46)		
Common Serotypes - Serotype 23F	487.51 (356.25 to 667.13)	3679.67 (2971.61 to 4556.44)		
Additional Serotypes - Serotype 1	62.63 (47.59 to 82.41)	294.07 (226.88 to 381.15)		
Additional Serotypes - Serotype 3	176.07 (144.89 to 213.96)	504.66 (435.71 to 584.53)		
Additional Serotypes - Serotype 5	127.11 (99.36 to 162.6)	333.24 (274.24 to 404.94)		
Additional Serotypes - Serotype 6A	541.81 (392.09 to 748.68)	2217.29 (1821.95 to 2698.42)		
Additional Serotypes - Serotype 7F	5914.33 (4710.83 to 7425.3)	14886.35 (12560.25 to 17643.22)		

Additional Serotypes - Serotype 19A	157.59 (118.91 to 208.84)	1415.08 (1140.56 to 1755.66)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were recorded from the signing of the Informed Consent Form (ICF) to 1 month after dose 2 and from toddler dose until toddler dose blood draw. All SAEs were recorded from the signing of the ICF to 6 months after the final study vaccination

Adverse event reporting additional description:

Version was not captured, here 0.0 is mentioned for dictionary version. Local Reactions (LRs) and systemic events (SEs) were to be assessed only for infant series and toddler dose groups.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	7vPnC Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 3 and 5 months. Adverse events were collected from dose 1 to approximately one month after dose 2.

Reporting group title	13vPnC Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 3 and 5 months. Adverse events were collected from dose 1 to approximately one month after dose 2.

Reporting group title	13vPnC Toddler Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 11 months of age. Adverse events were collected for approximately one month after toddler dose.

Reporting group title	7vPnC Toddler Series

Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 11 months of age. Adverse events were collected for approximately one month after toddler dose.

Reporting group title	13vPnC After Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 3 and 5 months. Adverse events (only any newly diagnosed chronic medical conditions) were collected from approximately one month after dose 2 to toddler dose.

Reporting group title	7vPnC After Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 3 and 5 months. Adverse events (only any newly diagnosed chronic medical conditions) were collected from approximately one month after dose 2 to toddler dose.

Reporting group title	13vPnC 6-Month Follow-up

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 3 and 5 months (infant series) and 11 months of age (toddler dose). Adverse events (any newly diagnosed chronic medical conditions, hospitalizations, and SAEs) were collected for approximately six months after last visit.

Reporting group title	7vPnC 6-Month Follow-up

Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 3 and 5 months (infant series) and 11 months of age (toddler dose). Adverse events (any newly diagnosed chronic medical conditions, hospitalizations, and SAEs) were collected for approximately six months after last visit.

Serious adverse events	7vPnC Infant Series	13vPnC Infant Series	13vPnC Toddler Series
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 302 (3.31%)	6 / 300 (2.00%)	3 / 284 (1.06%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (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
Asthma			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Dyspnoea			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Wheezing			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Laryngospasm			

subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Decreased activity			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Pelizaeus-Merzbacher disease			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			

subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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
Hypokinesia			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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
Nystagmus			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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
Febrile convulsion			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile spasms			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Meningism			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Syncope vasovagal			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Blood and lymphatic system disorders			
Microcytic anaemia			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Anal fissure			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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
Constipation			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	2 / 284 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Cough			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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	3 / 302 (0.99%)	2 / 300 (0.67%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 302 (0.33%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (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 rotavirus			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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	1 / 302 (0.33%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (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
Bronchopneumonia			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Kawasaki's disease			

subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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 adenovirus			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Bronchitis			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (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			
Failure to thrive			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (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
Dehydration			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	7vPnC Toddler Series	13vPnC After Infant Series	7vPnC After Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 281 (0.36%)	8 / 299 (2.68%)	11 / 302 (3.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Asthma			

subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (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
Decreased activity			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Congenital, familial and genetic disorders			
Pelizaeus-Merzbacher disease			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Hypokinesia			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Nystagmus			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Febrile convulsion			
subjects affected / exposed	0 / 281 (0.00%)	2 / 299 (0.67%)	0 / 302 (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
Infantile spasms			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningism			

subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope vasovagal			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Blood and lymphatic system disorders			
Microcytic anaemia			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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			
Anal fissure			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Constipation			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Vomiting			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (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
Diarrhoea			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	0 / 302 (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
Skin and subcutaneous tissue disorders			

Cough			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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			
subjects affected / exposed	0 / 281 (0.00%)	3 / 299 (1.00%)	2 / 302 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Upper respiratory tract infection			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (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
Bronchopneumonia			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	2 / 302 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki's disease			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
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 adenovirus			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Pharyngotonsillitis			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Bronchitis			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Epstein-Barr virus infection			

subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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			
Failure to thrive			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (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
Dehydration			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 299 (3.01%)	11 / 302 (3.64%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			

subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased activity			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Head injury			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Pelizaeus-Merzbacher disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokinesia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nystagmus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			

subjects affected / exposed	2 / 299 (0.67%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infantile spasms			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningism			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope vasovagal			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Microcytic anaemia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Anal fissure			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Cough			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 299 (0.00%)	4 / 302 (1.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Otitis media			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kawasaki's disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	1 / 299 (0.33%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 299 (0.33%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epstein-Barr virus infection			
subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis orbital			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 299 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	7vPnC Infant Series	13vPnC Infant Series	13vPnC Toddler Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	262 / 302 (86.75%)	271 / 300 (90.33%)	223 / 284 (78.52%)
Surgical and medical procedures			
Induration (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	60 / 209 (28.71%)	51 / 207 (24.64%)	0 / 284 (0.00%)
occurrences (all)	60	51	0
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	2 / 302 (0.66%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	23 / 302 (7.62%)	24 / 300 (8.00%)	25 / 284 (8.80%)
occurrences (all)	25	25	26
Injection site swelling			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Fever >39 degree C but <=40 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	11 / 233 (4.72%)	8 / 224 (3.57%)	16 / 167 (9.58%)
occurrences (all)	11	8	16
Fever >=38 degree C but <=39 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	95 / 246 (38.62%)	103 / 247 (41.70%)	130 / 204 (63.73%)
occurrences (all)	95	103	130
Fever >40 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 230 (0.00%)	0 / 222 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Irritability Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	165 / 259 (63.71%)	188 / 258 (72.87%)	165 / 221 (74.66%)
occurrences (all)	165	188	165
Decreased appetite Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	85 / 246 (34.55%)	87 / 246 (35.37%)	103 / 198 (52.02%)
occurrences (all)	85	87	103
Increased sleep Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	178 / 276 (64.49%)	177 / 269 (65.80%)	105 / 195 (53.85%)
occurrences (all)	178	177	105
Decreased sleep Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	88 / 242 (36.36%)	96 / 244 (39.34%)	64 / 180 (35.56%)
occurrences (all)	88	96	64
Fever >=38 degree C but <=39 degree C Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	137 / 226 (60.62%)	126 / 227 (55.51%)	0 / 284 (0.00%)
occurrences (all)	137	126	0
Fever >39 degree C but <=40	Additional description: Subjects affected and occurrences for SEs is same as		

degree C Dose 2 Infant Series	data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	14 / 201 (6.97%)	14 / 204 (6.86%)	0 / 284 (0.00%)
occurrences (all)	14	14	0
Irritability Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	183 / 243 (75.31%)	185 / 245 (75.51%)	0 / 284 (0.00%)
occurrences (all)	183	185	0
Decreased appetite Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	99 / 218 (45.41%)	104 / 220 (47.27%)	0 / 284 (0.00%)
occurrences (all)	99	104	0
Increased sleep Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	131 / 232 (56.47%)	129 / 226 (57.08%)	0 / 284 (0.00%)
occurrences (all)	131	129	0
Decreased sleep Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	89 / 213 (41.78%)	89 / 222 (40.09%)	0 / 284 (0.00%)
occurrences (all)	89	89	0
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	18 / 302 (5.96%)	18 / 300 (6.00%)	8 / 284 (2.82%)
occurrences (all)	19	19	8
Asthma			
subjects affected / exposed	0 / 302 (0.00%)	3 / 300 (1.00%)	1 / 284 (0.35%)
occurrences (all)	0	3	1
Rhonchi			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 302 (0.00%)	2 / 300 (0.67%)	0 / 284 (0.00%)
occurrences (all)	0	3	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Cardiac disorders			
Extrasystoles			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Nervous system disorders			
Nystagmus			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	4 / 302 (1.32%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	4	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	12 / 302 (3.97%)	5 / 300 (1.67%)	8 / 284 (2.82%)
occurrences (all)	14	5	8
Vomiting			
subjects affected / exposed	5 / 302 (1.66%)	1 / 300 (0.33%)	4 / 284 (1.41%)
occurrences (all)	5	1	4
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 302 (0.66%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	2	1	0
Abdominal pain			
subjects affected / exposed	2 / 302 (0.66%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Frequent bowel movements			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Perianal erythema			

subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Infantile colic			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Regurgitation			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	5 / 302 (1.66%)	3 / 300 (1.00%)	0 / 284 (0.00%)
occurrences (all)	5	3	0
Eczema			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	2 / 284 (0.70%)
occurrences (all)	0	1	2
Skin fissures			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Skin lesion			

subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Tenderness (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	73 / 243 (30.04%)	75 / 234 (32.05%)	94 / 199 (47.24%)
occurrences (all)	74	75	94
Tenderness (Significant) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	8 / 231 (3.46%)	6 / 224 (2.68%)	14 / 164 (8.54%)
occurrences (all)	8	6	14
Induration (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	47 / 240 (19.58%)	44 / 232 (18.97%)	50 / 175 (28.57%)
occurrences (all)	47	44	50
Induration (Mild) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	44 / 244 (18.03%)	41 / 232 (17.67%)	46 / 174 (26.44%)
occurrences (all)	44	41	46
Induration (Moderate) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[19]	7 / 229 (3.06%)	8 / 223 (3.59%)	12 / 160 (7.50%)
occurrences (all)	7	8	12
Erythema (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	65 / 245 (26.53%)	60 / 233 (25.75%)	65 / 178 (36.52%)
occurrences (all)	65	60	65
Erythema (Mild) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	60 / 244 (24.59%)	56 / 233 (24.03%)	58 / 178 (32.58%)
occurrences (all)	60	56	58
Erythema (Moderate) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	7 / 231 (3.03%)	6 / 222 (2.70%)	12 / 160 (7.50%)
occurrences (all)	7	6	12
Tenderness (Significant) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	10 / 199 (5.03%)	9 / 199 (4.52%)	0 / 284 (0.00%)
occurrences (all)	10	9	0
Tenderness (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	79 / 215 (36.74%)	65 / 214 (30.37%)	0 / 284 (0.00%)
occurrences (all)	79	65	0
Induration (Moderate) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	10 / 195 (5.13%) 10	11 / 198 (5.56%) 11	0 / 284 (0.00%) 0
Induration (Mild) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[26] occurrences (all)	55 / 208 (26.44%) 55	45 / 207 (21.74%) 45	0 / 284 (0.00%) 0
Erythema (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	73 / 212 (34.43%) 73	67 / 213 (31.46%) 67	0 / 284 (0.00%) 0
Erythema (Mild) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[28] occurrences (all)	68 / 211 (32.23%) 68	60 / 211 (28.44%) 60	0 / 284 (0.00%) 0
Erythema (Moderate) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[29] occurrences (all)	7 / 195 (3.59%) 7	11 / 200 (5.50%) 11	0 / 284 (0.00%) 0
Renal and urinary disorders Urinary tract pain subjects affected / exposed occurrences (all)	0 / 302 (0.00%) 0	1 / 300 (0.33%) 1	0 / 284 (0.00%) 0
Endocrine disorders			

Thyroid cyst			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	10 / 302 (3.31%)	13 / 300 (4.33%)	4 / 284 (1.41%)
occurrences (all)	10	13	4
Rhinitis			
subjects affected / exposed	10 / 302 (3.31%)	11 / 300 (3.67%)	9 / 284 (3.17%)
occurrences (all)	11	11	9
Bronchiolitis			
subjects affected / exposed	9 / 302 (2.98%)	8 / 300 (2.67%)	0 / 284 (0.00%)
occurrences (all)	9	8	0
Bronchitis			
subjects affected / exposed	5 / 302 (1.66%)	6 / 300 (2.00%)	3 / 284 (1.06%)
occurrences (all)	5	6	4
Pharyngitis			
subjects affected / exposed	6 / 302 (1.99%)	8 / 300 (2.67%)	2 / 284 (0.70%)
occurrences (all)	7	9	2
Gastroenteritis			
subjects affected / exposed	4 / 302 (1.32%)	4 / 300 (1.33%)	5 / 284 (1.76%)
occurrences (all)	4	4	5
Nasopharyngitis			
subjects affected / exposed	6 / 302 (1.99%)	4 / 300 (1.33%)	1 / 284 (0.35%)
occurrences (all)	6	5	1
Exanthema subitum			
subjects affected / exposed	3 / 302 (0.99%)	4 / 300 (1.33%)	0 / 284 (0.00%)
occurrences (all)	3	4	0
Ear infection			
subjects affected / exposed	2 / 302 (0.66%)	4 / 300 (1.33%)	6 / 284 (2.11%)
occurrences (all)	2	4	6
Influenza			

subjects affected / exposed	5 / 302 (1.66%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	5	1	0
Varicella			
subjects affected / exposed	3 / 302 (0.99%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	3	1	0
Urinary tract infection			
subjects affected / exposed	2 / 302 (0.66%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	3	1	0
Oral candidiasis			
subjects affected / exposed	1 / 302 (0.33%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	1	1	0
Otitis media			
subjects affected / exposed	2 / 302 (0.66%)	0 / 300 (0.00%)	2 / 284 (0.70%)
occurrences (all)	2	0	2
Sinusitis			
subjects affected / exposed	1 / 302 (0.33%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	1	1	0
Viral skin infection			
subjects affected / exposed	0 / 302 (0.00%)	2 / 300 (0.67%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Tracheitis			
subjects affected / exposed	2 / 302 (0.66%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	2	0	1
Impetigo			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	3 / 284 (1.06%)
occurrences (all)	1	0	3
Laryngitis			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Pharyngotonsillitis			

subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	1	0	1
Tonsillitis			
subjects affected / exposed	1 / 302 (0.33%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Enteritis infectious			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Roseola			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Bronchospasm			

subjects affected / exposed	3 / 302 (0.99%)	2 / 300 (0.67%)	0 / 284 (0.00%)
occurrences (all)	3	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 302 (0.00%)	1 / 300 (0.33%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Anorexia			
subjects affected / exposed	0 / 302 (0.00%)	0 / 300 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1

Non-serious adverse events	7vPnC Toddler Series	13vPnC After Infant Series	7vPnC After Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	230 / 281 (81.85%)	96 / 299 (32.11%)	90 / 302 (29.80%)
Surgical and medical procedures			
Induration (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	16 / 281 (5.69%)	33 / 299 (11.04%)	34 / 302 (11.26%)
occurrences (all)	17	40	43
Injection site swelling			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Fever >39 degree C but <=40 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[2]	20 / 160 (12.50%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	20	0	0
Fever >=38 degree C but <=39 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[3]	103 / 197 (52.28%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	103	0	0
Fever >40 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[4]	1 / 152 (0.66%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	1	0	0
Irritability Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[5]	170 / 227 (74.89%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	170	0	0
Decreased appetite Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[6]	113 / 197 (57.36%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	113	0	0
Increased sleep Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[7]	107 / 196 (54.59%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	107	0	0
Decreased sleep Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	61 / 171 (35.67%) 61	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Fever >=38 degree C but <=39 degree C Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Fever >39 degree C but <=40 degree C Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Irritability Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Decreased appetite Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Increased sleep Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[13]	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 281 (2.49%)	8 / 299 (2.68%)	7 / 302 (2.32%)
occurrences (all)	7	8	7
Asthma			
subjects affected / exposed	0 / 281 (0.00%)	3 / 299 (1.00%)	1 / 302 (0.33%)
occurrences (all)	0	3	1
Rhonchi			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	1 / 302 (0.33%)
occurrences (all)	0	1	2
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Extrasystoles			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Nystagmus			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 281 (1.07%)	2 / 299 (0.67%)	5 / 302 (1.66%)
occurrences (all)	3	2	5
Vomiting			
subjects affected / exposed	1 / 281 (0.36%)	1 / 299 (0.33%)	3 / 302 (0.99%)
occurrences (all)	1	1	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	2 / 281 (0.71%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	2	0	0
Flatulence			

subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Perianal erythema			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	3 / 302 (0.99%)
occurrences (all)	0	1	3
Nausea			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			

subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	1 / 281 (0.36%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	1 / 281 (0.36%)	1 / 299 (0.33%)	2 / 302 (0.66%)
occurrences (all)	1	1	2
Skin fissures			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	2 / 302 (0.66%)
occurrences (all)	0	0	2
Tenderness (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	83 / 188 (44.15%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	83	0	0
Tenderness (Significant) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	9 / 153 (5.88%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	9	0	0
Induration (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[17]	45 / 165 (27.27%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	45	0	0
Induration (Mild) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[18]	35 / 161 (21.74%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	35	0	0
Induration (Moderate) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[19]	16 / 157 (10.19%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	16	0	0
Erythema (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[20]	63 / 174 (36.21%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	63	0	0
Erythema (Mild) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[21]	53 / 172 (30.81%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	53	0	0
Erythema (Moderate) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[22]	17 / 156 (10.90%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	17	0	0
Tenderness (Significant) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Tenderness (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Induration (Moderate) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Induration (Mild) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[26] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Erythema (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	0 / 281 (0.00%) 0	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0
Erythema (Mild) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed[28]	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Urinary tract pain			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Thyroid cyst			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	7 / 281 (2.49%)	8 / 299 (2.68%)	12 / 302 (3.97%)
occurrences (all)	8	9	14
Rhinitis			
subjects affected / exposed	5 / 281 (1.78%)	6 / 299 (2.01%)	4 / 302 (1.32%)
occurrences (all)	6	6	5
Bronchiolitis			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 281 (0.36%)	4 / 299 (1.34%)	8 / 302 (2.65%)
occurrences (all)	1	4	9
Pharyngitis			
subjects affected / exposed	11 / 281 (3.91%)	16 / 299 (5.35%)	7 / 302 (2.32%)
occurrences (all)	11	18	8

Gastroenteritis			
subjects affected / exposed	1 / 281 (0.36%)	4 / 299 (1.34%)	5 / 302 (1.66%)
occurrences (all)	1	4	5
Nasopharyngitis			
subjects affected / exposed	2 / 281 (0.71%)	0 / 299 (0.00%)	3 / 302 (0.99%)
occurrences (all)	2	0	3
Exanthema subitum			
subjects affected / exposed	0 / 281 (0.00%)	16 / 299 (5.35%)	22 / 302 (7.28%)
occurrences (all)	0	16	22
Ear infection			
subjects affected / exposed	7 / 281 (2.49%)	7 / 299 (2.34%)	7 / 302 (2.32%)
occurrences (all)	7	8	7
Influenza			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	1 / 302 (0.33%)
occurrences (all)	0	1	1
Varicella			
subjects affected / exposed	0 / 281 (0.00%)	8 / 299 (2.68%)	5 / 302 (1.66%)
occurrences (all)	0	8	5
Urinary tract infection			
subjects affected / exposed	1 / 281 (0.36%)	3 / 299 (1.00%)	5 / 302 (1.66%)
occurrences (all)	1	4	6
Oral candidiasis			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	1 / 302 (0.33%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Viral skin infection			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	1 / 281 (0.36%)	1 / 299 (0.33%)	1 / 302 (0.33%)
occurrences (all)	1	1	1

Impetigo			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	1 / 281 (0.36%)	2 / 299 (0.67%)	0 / 302 (0.00%)
occurrences (all)	1	3	0
Pharyngotonsillitis			
subjects affected / exposed	1 / 281 (0.36%)	3 / 299 (1.00%)	0 / 302 (0.00%)
occurrences (all)	1	3	0
Tonsillitis			
subjects affected / exposed	1 / 281 (0.36%)	2 / 299 (0.67%)	1 / 302 (0.33%)
occurrences (all)	1	2	1
Enteritis infectious			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	2 / 302 (0.66%)
occurrences (all)	0	0	2
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	2 / 302 (0.66%)
occurrences (all)	0	0	2
Erythema infectiosum			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	1 / 302 (0.33%)
occurrences (all)	0	1	1
Acute tonsillitis			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	0	1	0
Bronchopneumonia			
subjects affected / exposed	1 / 281 (0.36%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	0 / 281 (0.00%)	1 / 299 (0.33%)	0 / 302 (0.00%)
occurrences (all)	0	1	0

Gastroenteritis viral			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences (all)	0	0	2
Roseola			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	1 / 302 (0.33%)
occurrences (all)	1	0	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 281 (0.36%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	1	0	0
Anorexia			
subjects affected / exposed	0 / 281 (0.00%)	0 / 299 (0.00%)	0 / 302 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
Surgical and medical procedures			
Induration (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Irritability			

subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Fever >39 degree C but <=40 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Fever >=38 degree C but <=39 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Fever >40 degree C Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Irritability Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Decreased appetite Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[6] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Increased sleep Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Decreased sleep Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Fever >=38 degree C but <=39 degree C Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Fever >39 degree C but <=40 degree C Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Irritability Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[11]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Decreased appetite Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Increased sleep Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Decreased sleep Dose 2 Infant Series	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Asthma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Rhonchi			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	

Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Pharyngolaryngeal pain subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Wheezing subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Psychiatric disorders Sleep disorder subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Cardiac disorders Extrasystoles subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Nervous system disorders Nystagmus subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Vomiting			

subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Frequent bowel movements			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Haematochezia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Gingival pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Perianal erythema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Infantile colic			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Regurgitation			

subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	1 / 299 (0.33%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Skin fissures			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Skin lesion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Induration (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[17] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Induration (Mild) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[18] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Induration (Moderate) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Erythema (Any) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Erythema (Mild) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed[21]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate) Dose 1 Infant Series and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Induration (Mild) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Erythema (Any) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Erythema (Mild) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[28] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Erythema (Moderate) Dose 2 Infant Series	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[29] occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Renal and urinary disorders Urinary tract pain subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Endocrine disorders Thyroid cyst subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Musculoskeletal and connective tissue disorders Muscle spasms subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	
Rhinitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 302 (0.00%) 0	

Bronchiolitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Exanthema subitum			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Varicella			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	

Sinusitis				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Viral skin infection				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Tracheitis				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Impetigo				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Fungal skin infection				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Otitis media acute				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Laryngitis				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Pharyngotonsillitis				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Tonsillitis				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Enteritis infectious				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Hand-foot-and-mouth disease				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		
Erythema infectiosum				
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)		
occurrences (all)	0	0		

Acute tonsillitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Bronchopneumonia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Roseola			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Bronchospasm			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	0	
Anorexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 302 (0.00%)	
occurrences (all)	0	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.
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 March 2007	Secondary objective was added to allow for an immunogenicity analysis of the 13vPnC and 7vPnC groups on serum samples collected after the toddler dose; the responses of 13vPnC relative to 7vPnC were to be measured. The statistics section was updated to state that the secondary endpoints for each of the pneumococcal serotypes were the proportion of subjects with a serotype specific IgG antibody concentration ≥0.35 µg/mL and the geometric mean IgG antibody concentration measured 1 month after the toddler dose.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported