Clinical trial results:
A Phase 3, Randomised, Active-Controlled, Double-Blind Trial Evaluating the Safety, Tolerability and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given With Routine Paediatric Vaccinations in India

Summary

EudraCT number	2008-003687-20
Trial protocol	Outside EU/EEA
Global end of trial date	13 October 2009

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	05 August 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-011

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00452790
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851002

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., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 May 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 October 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To assess the pneumococcal immune responses induced by 13-Valent Pneumococcal Conjugate Vaccine (13vPnC) relative to the pneumococcal immune responses induced by 7-Valent Pneumococcal Conjugate Vaccine (7vPnC) when measured 1 month after the infant series.
- To assess the immune responses induced by diphtheria, tetanus, whole cell pertussis; Haemphilus influenzae (H influenzae) type b (Hib); and hepatitis B vaccine (DTP-Hib-HBV) given with 13vPnC relative to the immune responses induced by DTP-Hib-HBV given with 7vPnC when measured 1 month after the infant series. The following antigens in DTP-Hib-HBV will be assessed: pertussis antigens (pertussis toxoid [PT], filamentous haemagglutinin [FHA], and pertactin [PRN]).

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 July 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	India: 709
Worldwide total number of subjects	709
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	709
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

708 subjects were enrolled and 709 were randomized into the study. One infant in the 13vPnC group was randomly assigned twice because of technical difficulties with the first random assignment. Though this infant participated in the study only once, both random assignments were included in the 354 subjects in the 13vPnC group.

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 1 single dose of 13vPnC, at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine containing diphtheria, tetanus, whole cell pertussis; H influenzae type b and hepatitis B vaccine (DTP-Hib-HBV); and a commercially available oral polio vaccine (OPV).

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

Dosage and administration details:

Subjects received 0.5 milliliter (mL) dose of 13vPnC at 6, 10 and 14 weeks of age.

Investigational medicinal product name	DTP-Hib-HBV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received DTP-Hib-HBV dose at 6, 10 and 14 weeks of age.

Investigational medicinal product name	OPV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects received OPV dose at 6, 10 and 14 weeks of age.

Arm title	7vPnC: Infant Series

Arm description:

Subjects received 1 single dose of 7vPnC at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine DTP-Hib-HBV and a commercially available OPV.

Arm type	Active comparator

Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of 7vPnC at 6, 10 and 14 weeks of age.

Investigational medicinal product name	DTP-Hib-HBV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received DTP-Hib-HBV dose at 6, 10 and 14 weeks of age.

Investigational medicinal product name	OPV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects received OPV dose at 6, 10 and 14 weeks of age.

Number of subjects in period 1	13vPnC: Infant series	7vPnC: Infant Series
Started	354	355
Vaccinated Dose 1	353	353
Vaccinated Dose 2	300	300
Vaccinated Dose 3	221	218
Completed	219	214
Not completed	135	141
Clinical hold - consent withdrawn	118	123
Failed to return	4	1
Adverse Event	1	2
Parent/legal guardian request	8	6
'Protocol Violation '	1	3
Other reasons	1	2
Lost to follow-up	2	2
'Death '	-	1
Investigator request	-	1

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

Arms	
Are arms mutually exclusive?	Yes
Arm title	13vPnC: After Infant series

Arm description:

Subjects who received 1 single dose of 13vPnC at 6, 10 and 14 weeks of age, co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV in the infant seies.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC: After Infant series

Arm description:

Subjects who received 1 single dose of 7vPnC at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV in the 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	219	214
Completed	198	200
Not completed	21	14
Adverse Event	4	1
Failed to return	1	-
Parent/legal guardian request	1	3
Other reasons	1	-
Lost to follow-up	4	-
Investigator request	10	10

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 1 single dose of 13vPnC administered at 12 months of age.

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

Dosage and administration details:

Subjects received 0.5 mL dose of 13vPnC at 12 months of age.

Arm title	7vPnC: Toddler Dose

Arm description:

Subjects received 1 single dose of 7vPnC administered at 12 months of age.

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

Dosage and administration details:

Subjects received 0.5 mL dose of 7vPnC at 12 months of age.

Number of subjects in period 3	13vPnC: Toddler Dose	7vPnC: Toddler Dose
Started	198	200
Completed	198	198
Not completed	0	2
'Parent/legal guardian request '	-	1
Failed to return	-	1

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC: Infant series
Reporting group description:	
Subjects received 1 single dose of 13vPnC, at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine containing diphtheria, tetanus, whole cell pertussis; H influenzae type b and hepatitis B vaccine (DTP-Hib-HBV); and a commercially available oral polio vaccine (OPV).	
Reporting group title	7vPnC: Infant Series
Reporting group description:	
Subjects received 1 single dose of 7vPnC at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine DTP-Hib-HBV and a commercially available OPV.	

Reporting group values	13vPnC: Infant series	7vPnC: Infant Series	Total
Number of subjects	354	355	709
Age categorical			
Units: Subjects			
Age continuous			
Units: months			
arithmetic mean	1.6	1.6	
standard deviation	± 0.3	± 0.2	-
Gender categorical			
Units: Subjects			
Female	169	169	338
Male	184	186	370
Unknown	1	0	1
Age continuous			
Units: weeks			
arithmetic mean	7.1	7.2	
standard deviation	± 1.1	± 1.1	-

End points

End points reporting groups

Reporting group title	13vPnC: Infant series
Reporting group description:	
Subjects received 1 single dose of 13vPnC, at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine containing diphtheria, tetanus, whole cell pertussis; H influenzae type b and hepatitis B vaccine (DTP-Hib-HBV); and a commercially available oral polio vaccine (OPV).	
Reporting group title	7vPnC: Infant Series
Reporting group description:	
Subjects received 1 single dose of 7vPnC at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine DTP-Hib-HBV and a commercially available OPV.	
Reporting group title	13vPnC: After Infant series
Reporting group description:	
Subjects who received 1 single dose of 13vPnC at 6, 10 and 14 weeks of age, co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV in the infant seies.	
Reporting group title	7vPnC: After Infant series
Reporting group description:	
Subjects who received 1 single dose of 7vPnC at 6, 10 and 14 weeks of age co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV in the infant series.	
Reporting group title	13vPnC: Toddler Dose
Reporting group description:	
Subjects received 1 single dose of 13vPnC administered at 12 months of age.	
Reporting group title	7vPnC: Toddler Dose
Reporting group description:	
Subjects received 1 single dose of 7vPnC administered at 12 months of age.	

Primary: Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to (>=) 0.35 Micrograms per Milliliter (mcg/mL), 1 Month After the Infant Series.

End point title	Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to (>=) 0.35 Micrograms per Milliliter (mcg/mL), 1 Month After the Infant Series.[1]
End point description:	
Percentage of subjects achieving a predefined antibody level of >=0.35 mcg/mL along with the corresponding O'Brien-Fleming-adjusted, exact, 2-sided 95 percent (%) confidence interval (CI) for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F and 19 A) are presented. Evaluable immunogenicity population: had treatments as randomized at all 3 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations. n=number of subjects with determinate IgG antibody concentration for the specified serotype.	
End point type	Primary
End point timeframe:	
1 month after the infant series (18 weeks of age)	

Notes:

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

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	206	196		
Units: Percentage of subjects				
number (confidence interval 95.2%)				
Common serotypes - serotype 4 (n= 203, 192)	97 (93.6 to 98.9)	97.9 (94.7 to 99.4)		
Common serotypes - serotype 6B (n= 196,194)	84.7 (78.8 to 89.5)	87.1 (81.5 to 91.5)		
Common serotypes - serotype 9V (n= 204,195)	92.6 (88.1 to 95.8)	94.4 (90.1 to 97.2)		
Common serotypes - serotype 14 (n= 185,186)	91.4 (86.3 to 95)	93.5 (89 to 96.6)		
Common serotypes - serotype 18C (n= 204,188)	95.1 (91.1 to 97.6)	93.1 (88.4 to 96.3)		
Common serotypes - serotype 19F (n= 200,188)	95 (91 to 97.6)	94.7 (90.4 to 97.4)		
Common serotypes - serotype 23F (n= 202,186)	90.1 (85.1 to 93.9)	89.2 (83.8 to 93.3)		
Additional serotypes - serotype 1 (n= 206,195)	96.6 (93.1 to 98.6)	0.5 (0 to 2.8)		
Additional serotypes - serotype 3 (n= 201,187)	87.6 (82.1 to 91.8)	2.1 (0.6 to 5.4)		
Additional serotypes - serotype 5 (n= 201,185)	85.1 (79.3 to 89.7)	24.3 (18.3 to 31.2)		
Additional serotypes - serotype 6A (n= 200,191)	90 (84.9 to 93.8)	36.1 (29.3 to 43.4)		
Additional serotypes - serotype 7F (n= 203,192)	98 (95 to 99.5)	2.6 (0.8 to 6)		
Additional serotypes - serotype 19 A (n= 204,190)	99.5 (97.3 to 100)	84.7 (78.8 to 89.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving a Predefined Antibody Level for Concomitant Vaccine Pertussis Antigens (Pertussis Toxoid [PT], Filamentous Hemagglutinin [FHA], Pertactin [PRN]), 1 Month After the Infant Series.

End point title	Percentage of Subjects Achieving a Predefined Antibody Level for Concomitant Vaccine Pertussis Antigens (Pertussis Toxoid [PT], Filamentous Hemagglutinin [FHA], Pertactin [PRN]), 1 Month After the Infant Series.[2]

End point description:

Percentage of subjects achieving a predefined antibody level (measured in enzyme-linked immunosorbent assay [ELISA] units per mL [EU/mL]) along with the corresponding O'Brien-Fleming-adjusted, exact, 2-sided 95% CI for concomitant antigens pertussis (PT, FHA and PRN) are presented. Evaluable immunogenicity population: had treatments as randomized at all 3 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series (18 weeks of age)

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	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	206	196		
Units: Percentage of subjects				
number (confidence interval 95.2%)				
PT >=0.975 EU/mL	100 (98.2 to 100)	100 (98.1 to 100)		
FHA >=3.91 EU/mL	100 (98.2 to 100)	100 (98.1 to 100)		
PRN >=6 EU/mL	92.7 (88.2 to 95.9)	95.9 (92.1 to 98.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to 0.35 Mcg/mL, 1 Month After the Toddler Dose.

End point title	Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to 0.35 Mcg/mL, 1 Month After the Toddler Dose.

End point description:

Percentage of subjects achieving a predefined antibody level of >=0.35 mcg/mL along with the corresponding exact, 2-sided 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 19 A) are presented. Evaluable immunogenicity population: had treatments as randomized at all 4 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations. n=number of subjects with determinate IgG antibody concentration for the specified serotype.

End point type	Secondary

End point timeframe:

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

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	196		
Units: Percentage of subjects				
number (confidence interval 95%)				
Common serotypes - serotype 4 (n= 193, 196)	100 (98.1 to 100)	100 (98.1 to 100)		
Common serotypes - serotype 6B (n= 192,195)	100 (98.1 to 100)	99.5 (97.2 to 100)		
Common serotypes - serotype 9V (n= 193,196)	99.5 (97.1 to 100)	99.5 (97.2 to 100)		

Common serotypes - serotype 14 (n= 193,196)	99.5 (97.1 to 100)	99.5 (97.2 to 100)		
Common serotypes - serotype 18C (n= 193,196)	99.5 (97.1 to 100)	99 (96.4 to 99.9)		
Common serotypes - serotype 19F (n= 193,196)	97.9 (94.8 to 99.4)	98 (94.9 to 99.4)		
Common serotypes - serotype 23F (n= 193,196)	98.4 (95.5 to 99.7)	99.5 (97.2 to 100)		
Additional serotypes - serotype 1 (n= 193,195)	98.4 (95.5 to 99.7)	3.1 (1.1 to 6.6)		
Additional serotypes - serotype 3 (n= 193,194)	90.2 (85.1 to 94)	12.9 (8.5 to 18.4)		
Additional serotypes - serotype 5 (n= 192,183)	100 (98.1 to 100)	74.3 (67.4 to 80.5)		
Additional serotypes - serotype 6A (n= 193,194)	100 (98.1 to 100)	92.8 (88.2 to 96)		
Additional serotypes - serotype 7F (n= 193,194)	99 (96.3 to 99)	9.8 (6 to 14.9)		
Additional serotypes - serotype 19 A (n= 193,194)	100 (98.1 to 100)	98.5 (95.5 to 99.7)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 1 Month After the 3-Dose Infant Series

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 1 Month After the 3-Dose Infant Series

End point description:

Antibody GMC as measured in mcg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding O'Brien-Fleming-adjusted, 2-sided 95% CIs were calculated. Evaluable immunogenicity population: had treatments as randomized at all 3 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations. n=number of subjects with determinate IgG antibody concentration for the specified serotype.

End point type	Other pre-specified

End point timeframe:

1 month after the 3-dose infant series (18 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	206	196		
Units: mcg/mL				
geometric mean (confidence interval 95.2%)				
Common serotypes - serotype 4 (n= 203,192)	2.19 (1.95 to 2.46)	2.58 (2.26 to 2.95)		
Common serotypes - serotype 6B (n= 196,194)	1.45 (1.2 to 1.75)	1.56 (1.28 to 1.89)		

Common serotypes - serotype 9V (n= 204,195)	1.34 (1.19 to 1.5)	1.46 (1.28 to 1.65)		
Common serotypes - serotype 14 (n= 185,186)	2.84 (2.35 to 3.43)	2.39 (1.98 to 2.9)		
Common serotypes - serotype 18C (n= 204,188)	1.61 (1.42 to 1.82)	1.7 (1.47 to 1.96)		
Common serotypes - serotype 19F (n= 200,188)	2.25 (1.97 to 2.56)	2.47 (2.11 to 2.89)		
Common serotypes - serotype 23F (n= 202,186)	1.38 (1.18 to 1.6)	1.46 (1.25 to 1.7)		
Additional serotypes - serotype 1 (n= 206,195)	1.95 (1.72 to 2.22)	0.03 (0.03 to 0.04)		
Additional serotypes - serotype 3 (n= 201,187)	0.8 (0.72 to 0.9)	0.05 (0.05 to 0.06)		
Additional serotypes - serotype 5 (n= 201,185)	0.93 (0.82 to 1.06)	0.2 (0.18 to 0.23)		
Additional serotypes - serotype 6A (n= 200,191)	1.44 (1.25 to 1.66)	0.28 (0.25 to 0.31)		
Additional serotypes - serotype 7F (n= 203,192)	2.27 (2.05 to 2.33)	0.06 (0.05 to 0.06)		
Additional serotypes - serotype 19A (n= 204,190)	2.76 (2.46 to 3.1)	0.74 (0.66 to 0.82)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Antibody GMC as measured in mcg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% CIs were presented. Evaluable immunogenicity population: had treatments as randomized at all 4 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations. n=number of subjects with determinate IgG antibody concentration for the specified serotype.

End point type	Other pre-specified

End point timeframe:

1 month after toddler dose (13 months of age)

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	196		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4 (n= 193, 196)	5.33 (4.69 to 6.04)	5.85 (5.13 to 6.68)		

Common serotypes - serotype 6B (n= 192, 195)	12.24 (10.6 to 14.13)	11.6 (9.95 to 13.53)		
Common serotypes - serotype 9V (n= 193,196)	3.01 (2.68 to 3.37)	3.33 (2.96 to 3.75)		
Common serotypes - serotype 14 (n= 193,196)	10.59 (9.21 to 12.18)	10.95 (9.41 to 12.74)		
Common serotypes - serotype 18C (n= 193,196)	2.63 (2.33 to 2.97)	2.98 (2.65 to 3.34)		
Common serotypes - serotype 19F (n= 193,196)	8.38 (7.11 to 9.87)	5.65 (4.84 to 6.58)		
Common serotypes - serotype 23F (n= 193,196)	4.27 (3.66 to 4.98)	5.31 (4.66 to 6.04)		
Additional serotypes - serotype 1 (n= 193,195)	5.1 (4.39 to 5.92)	0.04 (0.04 to 0.05)		
Additional serotypes - serotype 3 (n= 193,194)	0.91 (0.81 to 1.03)	0.09 (0.08 to 0.11)		
Additional serotypes - serotype 5 (n= 192,183)	3.58 (3.2 to 4)	0.64 (0.55 to 0.75)		
Additional serotypes - serotype 6A (n= 193,194)	8.13 (7.11 to 9.28)	1.87 (1.62 to 2.17)		
Additional serotypes - serotype 7F (n= 193,194)	4.81 (4.27 to 5.42)	0.06 (0.05 to 0.08)		
Additional serotypes - serotype 19A (n= 193,194)	14.12 (12.45 to 16.01)	3.56 (3.14 to 4.05)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 1 (6 Weeks of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 1 (6 Weeks of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 centimeter [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (greater than [>] 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received dose 1 of the infant series vaccination (6 weeks of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the dose 1 of the infant series (6 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	353	353		
Units: Percentage of subjects				
number (not applicable)				
Tenderness: Any (n= 347,347)	62.5	59.7		

Tenderness: Significant (n= 341,343)	42.2	40.5		
Induration: Any (n= 339,342)	21.5	22.5		
Induration: Mild (n= 338,340)	19.2	19.1		
Induration: Moderate (n= 331,338)	4.8	5.6		
Induration: Severe (n= 329,336)	0	0		
Erythema: Any (n= 333,339)	12.6	13.3		
Erythema: Mild (n= 333,338)	11.4	11.8		
Erythema: Moderate (n= 330,337)	1.5	1.8		
Erythema: Severe (n= 329,336)	0	0		
Any of the above (n= 349,348)	66.8	65.2		

Statistical analyses

Statistical analysis title	Tenderness-any

Statistical analysis description:

Difference in incidence rates of tenderness-any within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.483
Method	Fisher exact

Statistical analysis title	Tenderness-significant

Statistical analysis description:

Difference in incidence rates of tenderness-significant within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.698
Method	Fisher exact

Statistical analysis title	Induration-any

Statistical analysis description:

Difference in incidence rates of induration-any within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.782
Method	Fisher exact

Statistical analysis title	Induration-mild

Statistical analysis description:

Difference in incidence rates of induration-mild within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Induration-moderate

Statistical analysis description:

Difference in incidence rates of induration-moderate within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.729
Method	Fisher exact

Statistical analysis title	Induration-severe

Statistical analysis description:

Difference in incidence rates of Induration-Severe within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [3]
Method	Fisher exact

Notes:

[3] - Here, "99999" in the p-value signifies not applicable, since no severe induration in both groups.

Statistical analysis title	Erythema-any

Statistical analysis description:

Difference in incidence rates of Erythema-Any within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.819
Method	Fisher exact

Statistical analysis title	Erythema-mild

Statistical analysis description:

Difference in incidence rates of erythema-mild within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.904
Method	Fisher exact

Statistical analysis title	Erythema-moderate

Statistical analysis description:

Difference in incidence rates of Erythema-Moderate within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Erythema-severe

Statistical analysis description:

Difference in incidence rates of erythema-severe within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [4]
Method	Fisher exact

Notes:

[4] - Here, "99999" in the p-value signifies not applicable, since no severe erythema in both groups".

Statistical analysis title	Any local reaction

Statistical analysis description:

Difference in incidence rates of any local reaction (tenderness, induration and erythema) within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.69
Method	Fisher exact

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 2 (10 Weeks of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 2 (10 Weeks of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 cm to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received the first 2 doses of the infant series vaccination (10 weeks of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the dose 2 of the infant series (10 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Percentage of subjects				
number (not applicable)				
Tenderness: Any (n= 284,282)	44.4	44		
Tenderness: Significant (n= 278,279)	26.6	28		
Induration: Any (n= 281,278)	20.6	18.7		
Induration: Mild (n= 281,277)	16.7	16.2		
Induration: Moderate (n= 273,272)	5.1	4		
Induration: Severe (n= 273,271)	0	0		
Erythema: Any (n= 275,280)	13.8	17.9		

Erythema: Mild (n= 275,279)	13.1	15.8		
Erythema: Moderate (n= 273,273)	1.5	2.9		
Erythema: Severe (n= 273,271)	0	0		
Any of the above (n= 285,286)	51.6	53.1		

Statistical analyses

Statistical analysis title	Tenderness-any

Statistical analysis description:

Difference in incidence rates of tenderness-any within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.933
Method	Fisher exact

Statistical analysis title	Tenderness-significant

Statistical analysis description:

Difference in incidence rates of tenderness-significant within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.776
Method	Fisher exact

Statistical analysis title	Induration-any

Statistical analysis description:

Difference in incidence rates of induration-any within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.596
Method	Fisher exact

Statistical analysis title	Induration-mild

Statistical analysis description:

Difference in incidence rates of induration-mild within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.909
Method	Fisher exact

Statistical analysis title	Induration-moderate

Statistical analysis description:

Difference in incidence rates of induration-moderate within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.683
Method	Fisher exact

Statistical analysis title	Induration-severe

Statistical analysis description:

Difference in incidence rates of induration-severe within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [5]
Method	Fisher exact

Notes:

[5] - Here, "99999" in the p-value signifies not applicable, since no severe induration in both groups.

Statistical analysis title	Erythema-any

Statistical analysis description:

Difference in incidence rates of erythema-any within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.203
Method	Fisher exact

Statistical analysis title	Erythema-mild

Statistical analysis description:

Difference in incidence rates of Erythema-Mild within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.399
Method	Fisher exact

Statistical analysis title	Erythema-moderate

Statistical analysis description:

Difference in incidence rates of erythema-moderate within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.382
Method	Fisher exact

Statistical analysis title	Erythema-severe

Statistical analysis description:

Difference in incidence rates of erythema-severe within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [6]
Method	Fisher exact

Notes:

[6] - Here, "99999" in the p-value signifies not applicable, since no severe erythema in both groups.

Statistical analysis title	Any local reaction

Statistical analysis description:

Difference in incidence rates of any Local reaction (tenderness, induration, erythema) within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.738
Method	Fisher exact

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 3 (14 Weeks of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 3 (14 Weeks of Age)

End point description:

Local reactions were reported using an electronic diary by the parent/legal guardian. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration and erythema present); Mild (0.5 cm to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received all 3 doses of the infant series vaccination (14 weeks of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the dose 3 of the infant series (14 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	221	218		
Units: Percentage of subjects				
number (not applicable)				
Tenderness: Any (n= 204,200)	37.3	38		
Tenderness: Significant (n= 199,196)	24.1	23.5		
Induration: Any (n= 198,195)	17.2	13.8		
Induration: Mild (n= 196,195)	15.8	11.8		
Induration: Moderate (n= 193,193)	2.6	3.6		
Induration: Severe (n= 191,193)	0	0		
Erythema: Any (n= 192,195)	10.4	9.7		
Erythema: Mild (n= 192,195)	10.4	9.2		
Erythema: Moderate (n= 191,193)	0	0.5		
Erythema: Severe (n= 191,193)	0	0		
Any of the above (n= 206,202)	43.2	42.1		

Statistical analyses

Statistical analysis title	Tenderness-any

Statistical analysis description:

Difference in incidence rates of tenderness-any within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.918
Method	Fisher exact

Statistical analysis title	Tenderness-significant

Statistical analysis description:

Difference in incidence rates of tenderness-significant within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.906
Method	Fisher exact

Statistical analysis title	Induration-any

Statistical analysis description:

Difference in incidence rates of induration-any within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.404
Method	Fisher exact

Statistical analysis title	Induration-mild

Statistical analysis description:

Difference in incidence rates of induration-mild within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.305
Method	Fisher exact

Statistical analysis title	Induration-moderate

Statistical analysis description:

Difference in incidence rates of induration-moderate within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.771
Method	Fisher exact

Statistical analysis title	Induration-severe

Statistical analysis description:

Difference in incidence rates of induration-severe within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [7]
Method	Fisher exact

Notes:

[7] - Here, "99999" in the p-value signifies not applicable, since no severe induration in both groups.

Statistical analysis title	Erythema-any

Statistical analysis description:

Difference in incidence rates of erythema-any within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.867
Method	Fisher exact

Statistical analysis title	Erythema-mild

Statistical analysis description:

Difference in incidence rates of erythema-mild within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.735
Method	Fisher exact

Statistical analysis title	Erythema-moderate

Statistical analysis description:

Difference in incidence rates of erythema-moderate within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Erythema-severe

Statistical analysis description:

Difference in incidence rates of erythema-severe within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [8]
Method	Fisher exact

Notes:

[8] - Here, "99999" in the p-value signifies not applicable, since no severe erythema in both groups.

Statistical analysis title	Any local reaction

Statistical analysis description:

Difference in incidence rates of any Local Reaction (tenderness, induration, erythema) within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.842
Method	Fisher exact

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

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

End point description:

Local reactions were reported using an electronic diary by the parent/legal guardian. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration and erythema present); Mild (0.5 cm to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received toddler dose vaccination(after 12 months). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198	200		
Units: Percentage of subjects				
number (not applicable)				
Tenderness: Any (n= 174,176)	29.9	30.7		
Tenderness: Significant (n= 171,170)	15.8	17.1		
Induration: Any (n= 173,176)	19.7	17.6		
Induration: Mild (n= 170,175)	15.9	14.9		
Induration: Moderate (n= 170,171)	5.3	7.6		
Induration: Severe (n= 167,169)	0	0		
Erythema: Any (n= 174,176)	14.9	14.2		
Erythema: Mild (n= 172,175)	12.2	10.9		
Erythema: Moderate (n= 169,170)	3.6	4.1		
Erythema: Severe (n= 167,169)	0	0		
Any of the above (n= 177,178)	36.7	41		

Statistical analyses

Statistical analysis title	Tenderness-any

Statistical analysis description:

Difference in incidence rates of tenderness-any within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.908
Method	Fisher exact

Statistical analysis title	Tenderness-significant

Statistical analysis description:

Difference in incidence rates of tenderness-significant within 4 days of the toddler dose, dose 4(12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.772
Method	Fisher exact

Statistical analysis title	Induration-any

Statistical analysis description:

Difference in incidence rates of induration-any within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.681
Method	Fisher exact

Statistical analysis title	Induration-mild

Statistical analysis description:

Difference in incidence rates of induration-mild within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.881
Method	Fisher exact

Statistical analysis title	Induration-moderate

Statistical analysis description:

Difference in incidence rates of induration-moderate within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.509
Method	Fisher exact

Statistical analysis title	Induration-severe

Statistical analysis description:

Difference in incidence rates of induration-severe within 4 days of the toddler dose (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [9]
Method	Fisher exact

Notes:

[9] - Here, "99999" in the p-value signifies not applicable, since no severe induration in both groups.

Statistical analysis title	Erythema-any

Statistical analysis description:

Difference in incidence rates of erythema-any within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.88
Method	Fisher exact

Statistical analysis title	Erythema-mild

Statistical analysis description:

Difference in incidence rates of erythema-mild within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.739
Method	Fisher exact

Statistical analysis title	Erythema-moderate

Statistical analysis description:

Difference in incidence rates of erythema-moderate within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Erythema-severe

Statistical analysis description:

Difference in incidence rates of erythema-severe within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [10]
Method	Fisher exact

Notes:

[10] - Here, "99999" in the p-value signifies not applicable, since no severe erythema in both groups.

Statistical analysis title	Any local reaction

Statistical analysis description:

Difference in incidence rates of any local reaction (tenderness, induration, erythema) within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.446
Method	Fisher exact

Other pre-specified: Percentage of Subjects With Pre-specified Systemic Events:

Infant Series Dose 1 (6 Weeks of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 1 (6 Weeks of Age)

End point description:

Systemic events (any fever >=38 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received at least dose 1 of the infant series vaccination (after 6 weeks). n=number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the dose 1 of the infant series (6 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	353	353		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C (n= 313,324)	19.8	21.6		
Fever >39 but <=40 degrees C (n= 309,322)	2.3	1.2		
Fever >40 degrees C (n= 309,322)	0.3	0.9		
Decreased appetite (n= 343,347)	55.7	55.9		
Irritability (n= 345,347)	83.2	79.8		
Increased sleep (n= 338,342)	40.8	36.8		
Decreased sleep (n= 336,343)	55.7	56		
Any systemic event (n= 350,348)	94.3	90.8		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Difference in incidence rates of fever >=38 but less than or equal to (<=) 39 degrees C within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.625
Method	Fisher exact

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >39 but <=40 degrees C within 4 days of the infant series dose 1

(6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.375
Method	Fisher exact

Statistical analysis title	Fever >40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >40 degrees C within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.624
Method	Fisher exact

Statistical analysis title	Decreased appetite

Statistical analysis description:

Difference in incidence rates of decreased appetite within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Irritability

Statistical analysis description:

Difference in incidence rates of irritability within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.282
Method	Fisher exact

Statistical analysis title	Increased sleep

Statistical analysis description:

Difference in incidence rates of Increased sleep within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.307
Method	Fisher exact

Statistical analysis title	Decreased sleep

Statistical analysis description:

Difference in incidence rates of decreased sleep within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.939
Method	Fisher exact

Statistical analysis title	Any systemic event

Statistical analysis description:

Difference in incidence rates of any systemic event (fever, decrease in appetite, irritability, increased or decreased sleep) within 4 days of the infant series dose 1 (6 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	706
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.085
Method	Fisher exact

Other pre-specified: Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 2 (10 Weeks of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 2 (10 Weeks of Age)

End point description:

Systemic events (any fever >=38 degrees C, decreased appetite, irritability, increased sleep, decreased

sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received dose 2 of the infant series vaccination (10 weeks of age); n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the dose 2 of the infant series (10 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C (n= 263,249)	10.3	15.3		
Fever >39 but <=40 degrees C (n= 259,247)	0.8	0.4		
Fever >40 degrees C (n= 259,247)	0	0.4		
Decreased appetite (n= 281,282)	48	46.5		
Irritability (n= 290,291)	70.7	69.8		
Increased sleep (n= 285,275)	33.7	26.9		
Decreased sleep (n= 282,286)	37.9	46.9		
Any systemic event (n= 294,297)	80.6	80.5		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Difference in incidence rates of fever >= 38 but <= 39 degrees C within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.111
Method	Fisher exact

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >39 but <= 40 degrees C within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fever >40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >40 degrees C within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.488
Method	Fisher exact

Statistical analysis title	Decreased appetite

Statistical analysis description:

Difference in incidence rates of Decreased appetite within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.736
Method	Fisher exact

Statistical analysis title	Irritability

Statistical analysis description:

Difference in incidence rates of Irritability within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.856
Method	Fisher exact

Statistical analysis title	Increased sleep

Statistical analysis description:

Difference in incidence rates of Increased sleep within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.098
Method	Fisher exact

Statistical analysis title	Decreased sleep

Statistical analysis description:

Difference in incidence rates of Decreased sleep within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.034
Method	Fisher exact

Statistical analysis title	Any systemic event

Statistical analysis description:

Difference in incidence rates of Any systemic event (fever, decrease in appetite, irritability, increased or decreased sleep) within 4 days of the infant series dose 2 (10 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	600
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Other pre-specified: Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 3 (14 Weeks of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 3 (14 Weeks of Age)

End point description:

Systemic events (any fever >=38 degrees C, decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received dose 3 of the infant series vaccination (14 weeks of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the dose 3 of the infant series (14 weeks of age)

End point values	13vPnC: Infant series	7vPnC: Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	221	218		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C (n= 181,172)	7.7	14		
Fever >39 but <=40 degrees C (n= 179,170)	0	0		
Fever >40 degrees C (n= 179,171)	0	0.6		
Decreased appetite (n= 202,200)	42.1	41		
Irritability (n= 208,208)	64.4	67.3		
Increased sleep (n= 199,195)	20.1	20.5		
Decreased sleep (n= 205,201)	42.4	36.8		
Any systemic event (n= 213,209)	75.1	78.5		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Difference in incidence rates of fever >= 38 but <= 39 degrees C within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.085
Method	Fisher exact

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >39 but <= 40 degrees C within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [11]
Method	Fisher exact

Notes:

[11] - Here, "99999" in the p-value signifies not applicable, since no subject with fever > 39 but <= 40 degrees C in both groups.

Statistical analysis title	Fever >40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >40 degrees C within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.489
Method	Fisher exact

Statistical analysis title	Decreased appetite

Statistical analysis description:

Difference in incidence rates of decreased appetite within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.84
Method	Fisher exact

Statistical analysis title	Irritability

Statistical analysis description:

Difference in incidence rates of irritability within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.605
Method	Fisher exact

Statistical analysis title	Increased sleep

Statistical analysis description:

Difference in incidence rates of increased sleep within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Decreased sleep

Statistical analysis description:

Difference in incidence rates of decreased sleep within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.265
Method	Fisher exact

Statistical analysis title	Any systemic event

Statistical analysis description:

Difference in incidence rates of any systemic event (fever, decrease in appetite, irritability, increased or decreased sleep) within 4 days of the infant series dose 3 (14 weeks of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Infant series v 7vPnC: Infant Series
Number of subjects included in analysis	439
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.422
Method	Fisher exact

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

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

End point description:

Systemic events (any fever >=38 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received toddler dose vaccination (12 months of age).n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC: Toddler Dose	7vPnC: Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198	200		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C (n= 161,154)	5.6	6.5		
Fever >39 but <=40 degrees (n= 160,152)	0.6	0		
Fever >40 degrees C (n= 160,152)	0	0		
Decreased appetite (n= 174,179)	28.7	24.6		
Irritability (n= 174,183)	38.5	35		
Increased sleep (n= 171,170)	12.3	9.4		
Decreased sleep (n= 172,178)	22.7	27		
Any systemic event (n= 179,186)	54.7	52.7		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Difference in incidence rates of fever >= 38 but <= 39 degrees within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.815
Method	Fisher exact

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >39 but <= 40 degrees within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

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

Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.99
Method	Fisher exact

Statistical analysis title	Fever >40 degrees C

Statistical analysis description:

Difference in incidence rates of fever >40 degrees C within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 99999 [12]
Method	Fisher exact

Notes:

[12] - Here, "99999" in the p-value signifies not applicable, since no subject with fever > 40 degrees C in both groups.

Statistical analysis title	Decreased appetite

Statistical analysis description:

Difference in incidence rates of decreased appetite within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.401
Method	Fisher exact

Statistical analysis title	Irritability

Statistical analysis description:

Difference in incidence rates of irritability within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.511
Method	Fisher exact

Statistical analysis title	Increased sleep

Statistical analysis description:

Difference in incidence rates of increased sleep within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.487
Method	Fisher exact

Statistical analysis title	Decreased sleep

Statistical analysis description:

Difference in incidence rates of decreased sleep within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.388
Method	Fisher exact

Statistical analysis title	Any systemic event

Statistical analysis description:

Difference in incidence rates of any systemic event fever, decrease in appetite, irritability, increased or decreased sleep) within 4 days of the toddler dose, dose 4 (12 months of age) reported in the 13vPnC group relative to the incidence rates in the 7vPnC group. No hypothesis testing was performed. The analysis is descriptive.

Comparison groups	13vPnC: Toddler Dose v 7vPnC: Toddler Dose
Number of subjects included in analysis	398
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.753
Method	Fisher exact

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were recorded from signing of ICF to 1 month after infant series and toddler dose to 1 month after toddler dose. SAEs were recorded from signing of ICF to 1 month after toddler dose. Local and systemic events assessed within 4 days of each vaccination

Adverse event reporting additional description:

Safety population = all randomized subjects with at least 1 dose of study treatment. An Adverse Event (AE) term may be reported as both a serious and non-serious AE, but are distinct events. AE may = serious for 1 subject and = non-serious for another subject or subject may have experienced both a serious and non-serious episode of the same event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.1

Reporting groups

Reporting group title	Infant Series 13vPnC

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC, administered intramuscularly, at 6, 10 and 14 weeks of age (infant series), co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV.

Reporting group title	Infant Series 7vPnC

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC, administered intramuscularly, at 6, 10 and 14 weeks of age (infant series), co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV.

Reporting group title	After the Infant Series 13vPnC

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC, administered intramuscularly, at 6, 10 and 14 weeks of age (infant series), co-administered with a commercially available combination vaccine DTP-Hib-HBV and a commercially available OPV. AEs were collected from approximately 1 month after Dose 3 to the Toddler dose.

Reporting group title	After the Infant Series 7vPnC

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC, administered intramuscularly, at 6, 10 and 14 weeks of age (infant series), co-administered with a commercially available combination vaccine containing DTP-Hib-HBV and a commercially available OPV. AEs were collected from approximately 1 month after Dose 3 to the Toddler dose.

Reporting group title	Toddler Dose 13vPnC

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC, administered intramuscularly, at 12 months of age (toddler dose).

Reporting group title	Toddler Dose 7vPnC

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC, administered intramuscularly, at 12 months of age (toddler dose).

Serious adverse events	Infant Series 13vPnC	Infant Series 7vPnC	After the Infant Series 13vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 353 (2.27%)	6 / 353 (1.70%)	8 / 353 (2.27%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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			
Pneumonitis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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			
Breath holding			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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			
Heart disease congenital			

subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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			
Cardiac failure congestive			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (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
Cardiac arrest			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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			
Convulsion			
subjects affected / exposed	1 / 353 (0.28%)	1 / 353 (0.28%)	0 / 353 (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
Febrile convulsion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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
Status epilepticus			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Infantile colic			

subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (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
Diarrhoea			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 353 (0.57%)	4 / 353 (1.13%)	0 / 353 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	3 / 353 (0.85%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (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

Viral infection			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	2 / 353 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	2 / 353 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	2 / 353 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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
Sepsis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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
Septic shock			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			

subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (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			
Hypocalcaemia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (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
Dehydration			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	2 / 353 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	After the Infant Series 7vPnC	Toddler Dose 13vPnC	Toddler Dose 7vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 353 (3.12%)	4 / 198 (2.02%)	1 / 200 (0.50%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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 arrest			

subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (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
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	1 / 200 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Heart disease congenital			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Cardiac arrest			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Status epilepticus			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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			
Anaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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			
Infantile colic			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 353 (0.28%)	1 / 198 (0.51%)	0 / 200 (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
Meningitis bacterial			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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	4 / 353 (1.13%)	2 / 198 (1.01%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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
Dysentery			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Sepsis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Septic shock			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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 myocarditis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (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	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (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

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

Non-serious adverse events	Infant Series 13vPnC	Infant Series 7vPnC	After the Infant Series 13vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	330 / 353 (93.48%)	316 / 353 (89.52%)	5 / 353 (1.42%)
Vascular disorders			
Pallor			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Umbilical granuloma			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	75 / 353 (21.25%)	70 / 353 (19.83%)	0 / 353 (0.00%)
occurrences (all)	131	118	0
Injection site swelling			
subjects affected / exposed	55 / 353 (15.58%)	57 / 353 (16.15%)	0 / 353 (0.00%)
occurrences (all)	89	83	0
Pyrexia			
subjects affected / exposed	29 / 353 (8.22%)	21 / 353 (5.95%)	0 / 353 (0.00%)
occurrences (all)	31	22	0
Injection site erythema			
subjects affected / exposed	12 / 353 (3.40%)	12 / 353 (3.40%)	0 / 353 (0.00%)
occurrences (all)	15	14	0
Injection site nodule			
subjects affected / exposed	5 / 353 (1.42%)	12 / 353 (3.40%)	0 / 353 (0.00%)
occurrences (all)	5	12	0
Irritability			
subjects affected / exposed	1 / 353 (0.28%)	3 / 353 (0.85%)	0 / 353 (0.00%)
occurrences (all)	1	3	0
Tenderness			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Fever ≥38°C but ≤39°C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[1]	62 / 313 (19.81%)	70 / 324 (21.60%)	0 / 353 (0.00%)
occurrences (all)	62	70	0
Fever >39°C but ≤40°C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	7 / 309 (2.27%)	4 / 322 (1.24%)	0 / 353 (0.00%)
occurrences (all)	7	4	0
Fever >40°C Dose Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	1 / 309 (0.32%)	3 / 322 (0.93%)	0 / 353 (0.00%)
occurrences (all)	1	3	0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	191 / 343 (55.69%)	194 / 347 (55.91%)	0 / 353 (0.00%)
occurrences (all)	191	194	0
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	287 / 345 (83.19%)	277 / 347 (79.83%)	0 / 353 (0.00%)
occurrences (all)	287	277	0
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	138 / 338 (40.83%)	126 / 342 (36.84%)	0 / 353 (0.00%)
occurrences (all)	138	126	0
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[7]	187 / 336 (55.65%)	192 / 343 (55.98%)	0 / 353 (0.00%)
occurrences (all)	187	192	0
Fever ≥38°C but ≤39°C Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	27 / 263 (10.27%)	38 / 249 (15.26%)	0 / 353 (0.00%)
occurrences (all)	27	38	0
Fever >39°C but ≤40°C Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	2 / 259 (0.77%)	1 / 247 (0.40%)	0 / 353 (0.00%)
occurrences (all)	2	1	0
Decreased appetite Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	135 / 281 (48.04%)	131 / 282 (46.45%)	0 / 353 (0.00%)
occurrences (all)	135	131	0
Fever >40°C Dose Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 259 (0.00%)	1 / 247 (0.40%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Irritability Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	205 / 290 (70.69%)	203 / 291 (69.76%)	0 / 353 (0.00%)
occurrences (all)	205	203	0
Increased sleep Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used:			

Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	96 / 285 (33.68%)	74 / 275 (26.91%)	0 / 353 (0.00%)
occurrences (all)	96	74	0
Decreased sleep Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	107 / 282 (37.94%)	134 / 286 (46.85%)	0 / 353 (0.00%)
occurrences (all)	107	134	0
Fever ≥38°C but ≤39°C Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	14 / 181 (7.73%)	24 / 172 (13.95%)	0 / 353 (0.00%)
occurrences (all)	14	24	0
Fever >40°C Dose Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 179 (0.00%)	1 / 171 (0.58%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Decreased appetite Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	85 / 202 (42.08%)	82 / 200 (41.00%)	0 / 353 (0.00%)
occurrences (all)	85	82	0
Irritability Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	134 / 208 (64.42%)	140 / 208 (67.31%)	0 / 353 (0.00%)
occurrences (all)	134	140	0
Increased sleep Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	40 / 199 (20.10%) 40	40 / 195 (20.51%) 40	0 / 353 (0.00%) 0
Decreased sleep Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	87 / 205 (42.44%) 87	74 / 201 (36.82%) 74	0 / 353 (0.00%) 0
Immune system disorders			
Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 353 (0.00%) 0	0 / 353 (0.00%) 0	0 / 353 (0.00%) 0
Reproductive system and breast disorders			
Penile adhesion subjects affected / exposed occurrences (all)	1 / 353 (0.28%) 1	0 / 353 (0.00%) 0	0 / 353 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	37 / 353 (10.48%) 41	40 / 353 (11.33%) 49	0 / 353 (0.00%) 0
Upper airway obstruction subjects affected / exposed occurrences (all)	1 / 353 (0.28%) 1	3 / 353 (0.85%) 3	0 / 353 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	1 / 353 (0.28%) 1	1 / 353 (0.28%) 1	0 / 353 (0.00%) 0
Productive cough subjects affected / exposed occurrences (all)	1 / 353 (0.28%) 1	1 / 353 (0.28%) 1	0 / 353 (0.00%) 0
Wheezing subjects affected / exposed occurrences (all)	1 / 353 (0.28%) 1	1 / 353 (0.28%) 1	0 / 353 (0.00%) 0
Bronchial hyperreactivity			

subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences (all)	1	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Macrocephaly			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Phimosis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Crying			
subjects affected / exposed	1 / 353 (0.28%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	1	1	0
Convulsion			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0

Somnolence			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Febrile convulsion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 353 (0.28%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	1	1	0
Otorrhoea			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Eye discharge			
subjects affected / exposed	2 / 353 (0.57%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	2	1	0
Lacrimation increased			
subjects affected / exposed	2 / 353 (0.57%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	21 / 353 (5.95%)	26 / 353 (7.37%)	1 / 353 (0.28%)
occurrences (all)	24	29	1
Vomiting			
subjects affected / exposed	4 / 353 (1.13%)	6 / 353 (1.70%)	0 / 353 (0.00%)
occurrences (all)	4	6	0

Constipation			
subjects affected / exposed	1 / 353 (0.28%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	1	1	0
Infantile colic			
subjects affected / exposed	2 / 353 (0.57%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	3	0	0
Abdominal discomfort			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Perianal erythema			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	2 / 353 (0.57%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	2	2	0
Seborrhoeic dermatitis			
subjects affected / exposed	2 / 353 (0.57%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	3	2	0
Rash papular			
subjects affected / exposed	1 / 353 (0.28%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	1	2	0
Alopecia			
subjects affected / exposed	0 / 353 (0.00%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	2 / 353 (0.57%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	2	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 353 (0.00%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	0	2	0
Acne infantile			

subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Dandruff			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Rash generalised			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	1 / 353 (0.28%)
occurrences (all)	0	0	1
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	217 / 347 (62.54%)	207 / 347 (59.65%)	0 / 353 (0.00%)
occurrences (all)	217	207	0
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	144 / 341 (42.23%)	139 / 343 (40.52%)	0 / 353 (0.00%)
occurrences (all)	144	139	0
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[23]	73 / 339 (21.53%)	77 / 342 (22.51%)	0 / 353 (0.00%)
occurrences (all)	73	77	0
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	65 / 338 (19.23%)	65 / 340 (19.12%)	0 / 353 (0.00%)
occurrences (all)	65	65	0
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	16 / 331 (4.83%)	19 / 338 (5.62%)	0 / 353 (0.00%)
occurrences (all)	16	19	0
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	42 / 333 (12.61%)	45 / 339 (13.27%)	0 / 353 (0.00%)
occurrences (all)	42	45	0
Erythema (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	38 / 333 (11.41%)	40 / 338 (11.83%)	0 / 353 (0.00%)
occurrences (all)	38	40	0
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	5 / 330 (1.52%)	6 / 337 (1.78%)	0 / 353 (0.00%)
occurrences (all)	5	6	0
Tenderness (Any) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[29]	126 / 284 (44.37%)	124 / 282 (43.97%)	0 / 353 (0.00%)
occurrences (all)	126	124	0
Tenderness (Significant) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	74 / 278 (26.62%)	78 / 279 (27.96%)	0 / 353 (0.00%)
occurrences (all)	74	78	0
Induration (Any) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	58 / 281 (20.64%)	52 / 278 (18.71%)	0 / 353 (0.00%)
occurrences (all)	58	52	0
Induration (Mild) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	47 / 281 (16.73%)	45 / 277 (16.25%)	0 / 353 (0.00%)
occurrences (all)	47	45	0
Induration (Moderate) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	14 / 273 (5.13%)	11 / 272 (4.04%)	0 / 353 (0.00%)
occurrences (all)	14	11	0
Erythema (Any) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	38 / 275 (13.82%)	50 / 280 (17.86%)	0 / 353 (0.00%)
occurrences (all)	38	50	0
Erythema (Mild) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[35]	36 / 275 (13.09%)	44 / 279 (15.77%)	0 / 353 (0.00%)
occurrences (all)	36	44	0
Erythema (Moderate) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	4 / 273 (1.47%)	8 / 273 (2.93%)	0 / 353 (0.00%)
occurrences (all)	4	8	0
Tenderness (Any) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	76 / 204 (37.25%)	76 / 200 (38.00%)	0 / 353 (0.00%)
occurrences (all)	76	76	0
Tenderness (Significant) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	48 / 199 (24.12%)	46 / 196 (23.47%)	0 / 353 (0.00%)
occurrences (all)	48	46	0
Induration (Any) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	34 / 198 (17.17%)	27 / 195 (13.85%)	0 / 353 (0.00%)
occurrences (all)	34	27	0
Induration (Mild) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	31 / 196 (15.82%)	23 / 195 (11.79%)	0 / 353 (0.00%)
occurrences (all)	31	23	0
Induration (Moderate) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[41]	5 / 193 (2.59%)	7 / 193 (3.63%)	0 / 353 (0.00%)
occurrences (all)	5	7	0
Erythema (Any) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	20 / 192 (10.42%)	19 / 195 (9.74%)	0 / 353 (0.00%)
occurrences (all)	20	19	0
Erythema (Mild) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	20 / 192 (10.42%)	18 / 195 (9.23%)	0 / 353 (0.00%)
occurrences (all)	20	18	0
Erythema (Moderate) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 191 (0.00%)	1 / 193 (0.52%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Rickets			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Rhinitis			
subjects affected / exposed	47 / 353 (13.31%)	37 / 353 (10.48%)	0 / 353 (0.00%)
occurrences (all)	57	50	0
Upper respiratory tract infection			
subjects affected / exposed	39 / 353 (11.05%)	45 / 353 (12.75%)	2 / 353 (0.57%)
occurrences (all)	56	53	2
Nasopharyngitis			
subjects affected / exposed	11 / 353 (3.12%)	17 / 353 (4.82%)	0 / 353 (0.00%)
occurrences (all)	14	20	0
Gastroenteritis			

subjects affected / exposed	8 / 353 (2.27%)	5 / 353 (1.42%)	0 / 353 (0.00%)
occurrences (all)	10	5	0
Lower respiratory tract infection			
subjects affected / exposed	5 / 353 (1.42%)	2 / 353 (0.57%)	1 / 353 (0.28%)
occurrences (all)	5	2	1
Bronchiolitis			
subjects affected / exposed	4 / 353 (1.13%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	4	2	0
Respiratory tract infection			
subjects affected / exposed	2 / 353 (0.57%)	3 / 353 (0.85%)	0 / 353 (0.00%)
occurrences (all)	2	3	0
Bronchopneumonia			
subjects affected / exposed	2 / 353 (0.57%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	2	1	0
Otitis media			
subjects affected / exposed	2 / 353 (0.57%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	2	1	0
Viral infection			
subjects affected / exposed	2 / 353 (0.57%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	2	1	0
Acarodermatitis			
subjects affected / exposed	0 / 353 (0.00%)	2 / 353 (0.57%)	0 / 353 (0.00%)
occurrences (all)	0	2	0
Omphalitis			
subjects affected / exposed	1 / 353 (0.28%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	1	1	0
Viral diarrhoea			
subjects affected / exposed	2 / 353 (0.57%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	2	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 353 (0.28%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	1	1	0
Abscess neck			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Body tinea			

subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	1 / 353 (0.28%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	2	0	0
Fungal infection			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 353 (0.28%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	0 / 353 (0.00%)	1 / 353 (0.28%)	0 / 353 (0.00%)
occurrences (all)	0	1	0
Tuberculosis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	0 / 353 (0.00%)	0 / 353 (0.00%)	0 / 353 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	After the Infant Series 7vPnC	Toddler Dose 13vPnC	Toddler Dose 7vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 353 (2.55%)	98 / 198 (49.49%)	98 / 200 (49.00%)
Vascular disorders			
Pallor			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	1 / 200 (0.50%)
occurrences (all)	0	1	1
Pregnancy, puerperium and perinatal conditions			
Umbilical granuloma			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 353 (0.00%)	2 / 198 (1.01%)	6 / 200 (3.00%)
occurrences (all)	0	2	6
Injection site erythema			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Tenderness			

subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 353 (0.00%)	9 / 161 (5.59%)	10 / 154 (6.49%)
occurrences (all)	0	9	10
Fever >39°C but ≤40°C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 353 (0.00%)	1 / 160 (0.63%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Fever >40°C Dose Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 353 (0.00%)	0 / 160 (0.00%)	0 / 152 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 353 (0.00%)	50 / 174 (28.74%)	44 / 179 (24.58%)
occurrences (all)	0	50	44
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 353 (0.00%)	67 / 174 (38.51%)	64 / 183 (34.97%)
occurrences (all)	0	67	64
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[6]	0 / 353 (0.00%)	21 / 171 (12.28%)	16 / 170 (9.41%)
occurrences (all)	0	21	16
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 353 (0.00%)	39 / 172 (22.67%)	48 / 178 (26.97%)
occurrences (all)	0	39	48
Fever ≥38°C but ≤39°C Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Irritability Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type:			

Systematic			
subjects affected / exposed[12]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Increased sleep Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Irritability Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Increased sleep Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Penile adhesion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 353 (0.57%)	5 / 198 (2.53%)	6 / 200 (3.00%)
occurrences (all)	2	6	6
Upper airway obstruction			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Macrocephaly			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	1	0	0
Phimosis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Crying			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	2 / 200 (1.00%)
occurrences (all)	0	1	3
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye discharge			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	3 / 200 (1.50%)
occurrences (all)	0	1	3
Vomiting			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Perianal erythema			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Acne infantile			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Dandruff			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 353 (0.00%)	52 / 174 (29.89%)	54 / 176 (30.68%)
occurrences (all)	0	52	54
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[22]	0 / 353 (0.00%)	27 / 171 (15.79%)	29 / 170 (17.06%)
occurrences (all)	0	27	29
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 353 (0.00%)	34 / 173 (19.65%)	31 / 176 (17.61%)
occurrences (all)	0	34	31
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 353 (0.00%)	27 / 170 (15.88%)	26 / 175 (14.86%)
occurrences (all)	0	27	26
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 353 (0.00%)	9 / 170 (5.29%)	13 / 171 (7.60%)
occurrences (all)	0	9	13
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 353 (0.00%)	26 / 174 (14.94%)	25 / 176 (14.20%)
occurrences (all)	0	26	25
Erythema (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 353 (0.00%)	21 / 172 (12.21%)	19 / 175 (10.86%)
occurrences (all)	0	21	19
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1 and Toddler Dose: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[28]	0 / 353 (0.00%)	6 / 169 (3.55%)	7 / 170 (4.12%)
occurrences (all)	0	6	7
Tenderness (Any) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Erythema (Any) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[34]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Infant Series Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Erythema (Any) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Infant Series Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Rickets			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Rhinitis			
subjects affected / exposed	3 / 353 (0.85%)	1 / 198 (0.51%)	4 / 200 (2.00%)
occurrences (all)	3	1	4
Upper respiratory tract infection			

subjects affected / exposed	2 / 353 (0.57%)	11 / 198 (5.56%)	6 / 200 (3.00%)
occurrences (all)	2	13	6
Nasopharyngitis			
subjects affected / exposed	1 / 353 (0.28%)	1 / 198 (0.51%)	2 / 200 (1.00%)
occurrences (all)	1	1	2
Gastroenteritis			
subjects affected / exposed	0 / 353 (0.00%)	2 / 198 (1.01%)	3 / 200 (1.50%)
occurrences (all)	0	2	3
Lower respiratory tract infection			
subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	1 / 200 (0.50%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (0.00%)
occurrences (all)	0	1	0
Omphalitis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	1 / 200 (0.50%)
occurrences (all)	0	0	1
Abscess neck			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 353 (0.00%)	1 / 198 (0.51%)	0 / 200 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	0	0	0
Tuberculosis			

subjects affected / exposed	1 / 353 (0.28%)	0 / 198 (0.00%)	0 / 200 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	1 / 200 (0.50%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 353 (0.00%)	0 / 198 (0.00%)	1 / 200 (0.50%)
occurrences (all)	0	0	1

Notes:

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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 August 2007	1- Volume of blood samples reduced from 5mL to 3mL based on the actual weight of babies enrolled in the study as some infants were too small for a 5-mL blood draw at 18 weeks of age as specified in the study protocol. 2- An additional inclusion criterion of subject weight of 3.5 kg or greater at the time of enrollment was added.
13 February 2008	1- A cohort 2 was added to the study because the original subjects would not be fully representative of a 6-, 10-, and 14-week infant series schedule owing to the clinical hold. 2- Analysis endpoint for the pertussis responses was modified from the specific cutoff of 5 EU/mL to a comparison based on the level of serum IgG attained by 95% of subjects in the 7vPnC group. 3- Coprimary whole-cell pertussis antigens endpoint was changed to a primary endpoint. 4- A second interim analysis for the cohort 2 infant series was allowed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
10 October 2007	This study was placed temporarily on clinical hold to allow review of safety data. It was suspended based on the review of 4 serious adverse events (SAEs) reported as serious, unexpected, and possibly related by investigators from studies of 13vPnC or 7vPnC conducted outside of India. All 4 of the SAEs considered to be possibly related to vaccine by the investigator and reviewed by the Drug Controller General of India DCG(I) occurred in subjects who received the comparator 7vPnC, that is (ie), Prevenar.	01 December 2007
07 November 2008	The study was put temporarily on hold at all sites due to the death of a subject. This occurred 1 week after administration of the 14-week vaccination. The SAE was reported as possibly related to test article, and a report was generated. The investigator subsequently changed the causality assessment to “not related” to vaccination.	01 April 2009

Notes:

Limitations and caveats

None reported