Clinical trial results:
A Phase 3, Randomized, Double-blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine Manufactured With and Without Polysorbate 80 in Healthy Infants Given in a 2-, 3-, 4-, and 12-Month Schedule With Routine Pediatric Vaccinations

Summary

EudraCT number	2006-001685-16
Trial protocol	Outside EU/EEA
Global end of trial date	04 June 2008

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	31 July 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00366548
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851092

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 September 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 June 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) To demonstrate that the immune responses to the 13 common pneumococcal conjugates (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) induced by 13-valent pneumococcal conjugate vaccine (13vPnC) with polysorbate 80 (13vPnC+P80) were noninferior to the immune responses induced by 13vPnC without polysorbate 80 (13vPnC-P80) when measured 1 month after the infant series. 2) The safety objective of this study was to evaluate the acceptability of the safety profile of the 13vPnC+P80 and 13vPnC-P80, as measured by the incidence rates of local (injection site) reactions, systemic events, and adverse events (AEs).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 November 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 500
Worldwide total number of subjects	500
EEA total number of subjects	500

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)	500
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited in Poland from November 2006 to December 2006.

Pre-assignment

Screening details:

Subjects were enrolled into the study according to inclusion or exclusion criteria without a screening period.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC with (+) Polysorbate 80 Infant Series

Arm description:

Subjects received 13vPnC with (+) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	13vPnC + P80
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 milliliter (mL) dose of 13vPnC with P80 at approximately 2, 3 and 4 months of age.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) at 2, 3 and 4 months of age.

Investigational medicinal product name	Engerix B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age.

Arm title	13vPnC without (-) Polysorbate 80 Infant Series

Arm description:

Subjects received of 13vPnC without (-) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	13vPnC - P80
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of 13vPnC without P80 at approximately 2, 3 and 4 months of age.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) at 2, 3 and 4 months of age.

Investigational medicinal product name	Engerix B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age.

Number of subjects in period 1	13vPnC with (+) Polysorbate 80 Infant Series	13vPnC without (-) Polysorbate 80 Infant Series
Started	250	250
Vaccinated Dose 1	250	250
Vaccinated Dose 3	246	247
Vaccinated Dose 2	246	249
Completed	246	245
Not completed	4	5
Consent withdrawn by subject	3	1
Adverse Event	1	3
Protocol deviation	-	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 + Polysorbate 80 After Infant Series

Arm description:

Included subjects who received one single 0.5 mL dose of 13vPnC with P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC - Polysorbate 80 After Infant Series

Arm description:

Included subjects who received one single 0.5 mL dose of 13vPnC without P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC + Polysorbate 80 After Infant Series	13vPnC - Polysorbate 80 After Infant Series
Started	246	245
Completed	240	244
Not completed	6	1
Consent withdrawn by subject	3	1
Adverse Event	2	-
Lost to follow-up	1	-

Period 3	
Period 3 title	Toddler Dose
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms	
Are arms mutually exclusive?	Yes

Arm title	13vPnC+Polysorbate 80 After Toddler Dose

Arm description:

Subjects received 13vPnC with P80 coadministered with Priorix at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	13vPnC + P80
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of 13vPnC with P80 at approximately 12 months of age.

Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received one single 0.5 mL dose of combined vaccine containing attenuated measles, mumps, and rubella viruses (Priorix) at 12 months of age.

Arm title	13vPnC - Polysorbate 80 After Toddler Dose

Arm description:

Subjects received 13vPnC without P80 coadministered with Priorix at 12 months of age (toddler dose).

Arm type	Active comparator
Investigational medicinal product name	13vPnC - P80
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received one single 0.5 mL dose of 13vPnC without P80 at approximately 12 months of age.

Investigational medicinal product name	Priorix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received one single 0.5 mL dose of combined vaccine containing attenuated measles, mumps, and rubella viruses (Priorix) at 12 months of age.

Number of subjects in period 3	13vPnC+Polysorbate 80 After Toddler Dose	13vPnC - Polysorbate 80 After Toddler Dose
Started	240	244
Completed	240	244

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC with (+) Polysorbate 80 Infant Series
Reporting group description:	
Subjects received 13vPnC with (+) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.	
Reporting group title	13vPnC without (-) Polysorbate 80 Infant Series
Reporting group description:	
Subjects received of 13vPnC without (-) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.	

Reporting group values	13vPnC with (+) Polysorbate 80 Infant Series	13vPnC without (-) Polysorbate 80 Infant Series	Total
Number of subjects	250	250	500
Age categorical			
Units: Subjects			
Age continuous			
Units: months			
arithmetic mean	2.1	2.1	
standard deviation	± 0.5	± 0.5	-
Gender categorical			
Units: Subjects			
Female	122	122	244
Male	128	128	256

End points

End points reporting groups

Reporting group title	13vPnC with (+) Polysorbate 80 Infant Series
Reporting group description:	
Subjects received 13vPnC with (+) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.	
Reporting group title	13vPnC without (-) Polysorbate 80 Infant Series
Reporting group description:	
Subjects received of 13vPnC without (-) P80 coadministered with combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated Hib antigens (Pentaxim) and hepatitis B recombinant vaccine adsorbed (Engerix-B) at approximately 2 months of age, Pentaxim at approximately 3 months and 4 months of age.	
Reporting group title	13vPnC + Polysorbate 80 After Infant Series
Reporting group description:	
Included subjects who received one single 0.5 mL dose of 13vPnC with P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.	
Reporting group title	13vPnC - Polysorbate 80 After Infant Series
Reporting group description:	
Included subjects who received one single 0.5 mL dose of 13vPnC without P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months of age in infant series.	
Reporting group title	13vPnC+Polysorbate 80 After Toddler Dose
Reporting group description:	
Subjects received 13vPnC with P80 coadministered with Priorix at 12 months of age.	
Reporting group title	13vPnC - Polysorbate 80 After Toddler Dose
Reporting group description:	
Subjects received 13vPnC without P80 coadministered with Priorix at 12 months of age (toddler dose).	
Subject analysis set title	13vPnC + P80 Dose 1 Infant Series
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age (infant series, Dose 1).	
Subject analysis set title	13vPnC - P 80 Dose 1 Infant Series
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age (infant series, Dose 1).	
Subject analysis set title	13vPnC + P80 Dose 2 Infant Series
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 months age (infant series, Dose 2).	
Subject analysis set title	13vPnC - P80 Dose 2 Infant Series
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 months age (infant series, Dose 2).	
Subject analysis set title	13vPnC - P80 Dose 3 Infant Series
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series, Dose 3).	

Subject analysis set title	13vPnC + P80 Dose 3 Infant Series
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series, Dose 3).

Subject analysis set title	13vPnC + P80 Toddler Dose
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series), and Priorix at 12 months of age (toddler dose).

Subject analysis set title	13vPnC - P80 Toddler Dose
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant series), and Priorix at 12 months of age (toddler dose).

Primary: Percentage of Subjects Achieving Antibody Level Greater Than or Equal to (>=) 0.35 microgram per milliliter (µg/mL) in 13vPnC+P80 Group Relative to 13vPnC-80 Group After the Infant Series

End point title	Percentage of Subjects Achieving Antibody Level Greater Than or Equal to (>=) 0.35 microgram per milliliter (µg/mL) in 13vPnC+P80 Group Relative to 13vPnC-80 Group After the Infant Series

End point description:

Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold >=0.35 µg/mL along with the corresponding 95 percent (%) confidence interval (CI) for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) were presented. Evaluable immunogenicity population had valid and determinate assay results, and had no other major protocol violations, (n) = number of subjects with an antibody concentration >=0.35 micro gram per milliliter (mcg/mL) for the given serotype.

End point type	Primary

End point timeframe:

One month after 3-dose infant series (at 5 months of age)

End point values	13vPnC - Polysorbate 80 After Infant Series	13vPnC + Polysorbate 80 After Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238[1]	238[2]		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=222,224)	94.1 (90.3 to 96.7)	93.3 (89.3 to 96.1)		
Common Serotypes - Serotype 6B (n=145,158)	66.4 (60 to 72.4)	60.9 (54.4 to 67.2)		
Common Serotypes - Serotype 9V (n=231,232)	97.5 (94.6 to 99.1)	97.1 (94 to 98.8)		
Common Serotypes - Serotype 14 (n=225,232)	97.5 (94.6 to 99.1)	94.5 (90.8 to 97.1)		
Common Serotypes - Serotype 18C (n=233,233)	97.9 (95.2 to 99.3)	97.9 (95.2 to 99.3)		

Common Serotypes - Serotype 19F (n=228,234)	98.3 (95.8 to 99.5)	95.8 (92.4 to 98)		
Common Serotypes - Serotype 23F (n=205,220)	92.4 (88.3 to 95.5)	86.1 (81.1 to 90.3)		
Additional Serotypes - Serotype 1 (n=228,220)	92.4 (88.3 to 95.5)	95.8 (92.4 to 98)		
Additional Serotypes - Serotype 3 (n=233,236)	99.2 (97 to 99.9)	97.9 (95.2 to 99.3)		
Additional Serotypes - Serotype 5 (n=224,220)	92.4 (88.3 to 95.5)	94.1 (90.3 to 96.7)		
Additional Serotypes - Serotype 6A (n=206,205)	86.1 (81.1 to 90.3)	86.6 (81.6 to 90.6)		
Additional Serotypes - Serotype 7F (n=235,237)	99.6 (97.7 to 100)	98.7 (96.4 to 99.7)		
Additional Serotypes - Serotype 19A (n=235,238)	100 (98.5 to 100)	98.7 (96.4 to 99.7)		

Notes:

[1] - Subjects with a determinate antibody concentration for the specified serotype.

[2] - Subjects with a determinate antibody concentration for the specified serotype.

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in percentage
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.4
upper limit	3.7

Notes:

[3] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups greater than (>) -10%.

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in percentage
Point estimate	-5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.2
upper limit	3.3

Notes:

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

Statistical analysis title	Serotype 9V

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference in percentage
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	2.8

Notes:

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

Statistical analysis title	Serotype 14

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC - Polysorbate 80 After Infant Series v 13vPnC + Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Difference in percentage
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	0.7

Notes:

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

Statistical analysis title	Serotype 18C

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Difference in percentage
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	3

Notes:

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

Statistical analysis title	Serotype 19F

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Difference in percentage
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.1
upper limit	0.6

Notes:

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

Statistical analysis title	Serotype 23F

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Difference in percentage
Point estimate	-6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.1
upper limit	-0.7

Notes:

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

Statistical analysis title	Serotype 1

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series

Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Parameter estimate	Difference in percentage
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	7.9

Notes:

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

Statistical analysis title	Serotype 3

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	Difference in percentage
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	1.1

Notes:

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

Statistical analysis title	Serotype 5

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
Parameter estimate	Difference in percentage
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	6.4

Notes:

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

Statistical analysis title	Serotype 6A

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	Difference in percentage
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	6.7

Notes:

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

Statistical analysis title	Serotype 7F

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC - Polysorbate 80 After Infant Series v 13vPnC + Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
Parameter estimate	Difference in percentage
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	1.2

Notes:

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

Statistical analysis title	Serotype 19A

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
Parameter estimate	Difference in percentage
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	0.3

Notes:

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

Primary: Geometric Mean Antibody Concentration (GMC) in 13vPnC+P80 Group Relative to 13vPnC-P80 Group After the 3-Dose Infant Series

End point title	Geometric Mean Antibody Concentration (GMC) in 13vPnC+P80 Group Relative to 13vPnC-P80 Group After the 3-Dose Infant Series

End point description:

GMC as measured by enzyme-linked immunosorbent assay (ELISA) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) were presented. Evaluable immunogenicity population had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

1 month after 3-dose infant series (at 5 months of age)

End point values	13vPnC - Polysorbate 80 After Infant Series	13vPnC + Polysorbate 80 After Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238[16]	238[17]		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4	1.53 (1.36 to 1.72)	1.47 (1.3 to 1.65)		
Common Serotypes - Serotype 6B	0.57 (0.48 to 0.68)	0.51 (0.44 to 0.6)		
Common Serotypes - Serotype 9V	1.51 (1.38 to 1.65)	1.46 (1.34 to 1.6)		
Common Serotypes - Serotype 14	2.48 (2.2 to 2.8)	2.37 (2.06 to 2.73)		
Common Serotypes - Serotype 18C	1.87 (1.71 to 2.04)	1.84 (1.67 to 2.03)		
Common Serotypes - Serotype 19F	1.75 (1.6 to 1.91)	1.46 (1.3 to 1.65)		
Common Serotypes - Serotype 23F	1.11 (1 to 1.24)	0.93 (0.83 to 1.05)		
Additional Serotypes - Serotype 1	1.48 (1.32 to 1.66)	1.39 (1.26 to 1.55)		
Additional Serotypes - Serotype 3	1.62 (1.49 to 1.75)	1.5 (1.38 to 1.63)		
Additional Serotypes - Serotype 5	1.3 (1.16 to 1.44)	1.26 (1.13 to 1.4)		
Additional Serotypes - Serotype 6A	1.04 (0.92 to 1.17)	0.99 (0.88 to 1.12)		
Additional Serotypes - Serotype 7F	1.89 (1.73 to 2.06)	1.98 (1.81 to 2.15)		
Additional Serotypes - Serotype 19A	2.94 (2.69 to 3.21)	2.68 (2.44 to 2.95)		

Notes:

[16] - Subjects with a determinate IgG antibody concentration to the specified serotype.

[17] - Subjects with a determinate IgG antibody concentration to the specified serotype.

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
Parameter estimate	GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.13

Notes:

[18] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 9V
Statistical analysis description:	
GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
Parameter estimate	GMC ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.1

Notes:

[19] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 6B
Statistical analysis description:	
GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series

Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
Parameter estimate	GMC ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.14

Notes:

[20] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 14

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[21]
Parameter estimate	GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.15

Notes:

[21] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 18C

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[22]
Parameter estimate	GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.13

Notes:

[22] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 19F

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[23]
Parameter estimate	GMC ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.97

Notes:

[23] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 23F

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[24]
Parameter estimate	GMC ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.98

Notes:

[24] - Non-inferiority for each common serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 1

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[25]
Parameter estimate	GMC ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.1

Notes:

[25] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC/7vPnC) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 3
Statistical analysis description:	
GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[26]
Parameter estimate	GMC ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.04

Notes:

[26] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 6A
Statistical analysis description:	
GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[27]
Parameter estimate	GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.13

Notes:

[27] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 5
Statistical analysis description:	
GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.	
Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[28]
Parameter estimate	GMC ratio
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.13

Notes:

[28] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 7F

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
Parameter estimate	GMC ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.18

Notes:

[29] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Statistical analysis title	Serotype 19A

Statistical analysis description:

GMC ratio (13vPnC+P80/13vPnC-P80) was calculated.

Comparison groups	13vPnC + Polysorbate 80 After Infant Series v 13vPnC - Polysorbate 80 After Infant Series
Number of subjects included in analysis	476
Analysis specification	Pre-specified
Analysis type	non-inferiority[30]
Parameter estimate	GMC ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.04

Notes:

[30] - Non-inferiority for each additional serotype was declared if the lower limit of the 2-sided 95% CI for the GMC ratio (13vPnC+P80/13vPnC-P80) > 0.5 (2-fold criterion).

Secondary: Percentage of Subjects Achieving Antibody Level >=0.35 µg/mL in the 13vPnC Group After the Toddler Dose

End point title	Percentage of Subjects Achieving Antibody Level >=0.35 µg/mL in the 13vPnC Group After the Toddler Dose

End point description:

Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold >=0.35 µg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes

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

End point type	Secondary

End point timeframe:

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

End point values	13vPnC - Polysorbate 80 After Toddler Dose	13vPnC+Polysorbate 80 After Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238[31]	227[32]		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=226,238)	99.6 (97.7 to 100)	99.6 (97.6 to 100)		
Common Serotypes - Serotype 6B (n=225,237)	99.2 (97 to 99.9)	99.6 (97.5 to 100)		
Common Serotypes - Serotype 9V (n=226,238)	100 (98.5 to 100)	99.6 (97.6 to 100)		
Common Serotypes - Serotype 14 (n=226,238)	99.6 (97.7 to 100)	99.6 (97.6 to 100)		
Common Serotypes - Serotype 18C (n=226,238)	99.6 (97.7 to 100)	100 (98.4 to 100)		
Common Serotypes - Serotype 19F (n=226,237)	98.7 (96.3 to 99.7)	99.1 (96.8 to 99.9)		
Common Serotypes - Serotype 23F (n=226,238)	99.6 (97.7 to 100)	98.7 (96.2 to 99.7)		
Additional Serotypes - Serotype 1 (n=226,238)	99.2 (97 to 99.9)	100 (98.4 to 100)		
Additional Serotypes - Serotype 3 (n=223,236)	94.5 (90.8 to 97)	95.1 (91.3 to 97.5)		
Additional Serotypes - Serotype 5 (n=226,238)	100 (98.5 to 100)	99.6 (97.6 to 100)		
Additional Serotypes - Serotype 6A (n=226,237)	100 (98.5 to 100)	99.6 (97.6 to 100)		
Additional Serotypes - Serotype 7F (n=226,238)	100 (98.5 to 100)	100 (98.4 to 100)		
Additional Serotypes - Serotype 19A (n=226,238)	100 (98.5 to 100)	100 (98.4 to 100)		

Notes:

[31] - Subjects with a determinate antibody concentration for the specified serotype.

[32] - Subjects with a determinate antibody concentration for the specified serotype.

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose

Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[33]
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	1.9

Notes:

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

Statistical analysis title	Serotype 6B

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[34]
Parameter estimate	Difference in percentage
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	2.6

Notes:

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

Statistical analysis title	Serotype 9V

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[35]
Parameter estimate	Difference in percentage
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	1.1

Notes:

[35] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 14

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[36]
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	1.9

Notes:

[36] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 18C

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[37]
Parameter estimate	Difference in percentage
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	2.3

Notes:

[37] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 19F

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[38]
Parameter estimate	Difference in percentage
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	2.9

Notes:

[38] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 23F

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[39]
Parameter estimate	Difference in percentage
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	1.1

Notes:

[39] - Non-inferiority for each common serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 1

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[40]
Parameter estimate	Difference in percentage
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	3

Notes:

[40] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 3

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[41]
Parameter estimate	Difference in percentage
Point estimate	0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	4.9

Notes:

[41] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 5

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[42]
Parameter estimate	Difference in percentage
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	1.1

Notes:

[42] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 6A

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[43]
Parameter estimate	Difference in percentage
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	1.2

Notes:

[43] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 7F

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose

Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[44]
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	1.6

Notes:

[44] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Statistical analysis title	Serotype 19A

Statistical analysis description:

Difference in percentages between the two groups (13vPnC+P80 - 13vPnC-P80) was calculated.

Comparison groups	13vPnC+Polysorbate 80 After Toddler Dose v 13vPnC - Polysorbate 80 After Toddler Dose
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	non-inferiority[45]
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	1.6

Notes:

[45] - Non-inferiority for each additional serotype was declared if the lowest limit of the 2-sided 95% CI for the difference between the 2 groups > -10%.

Secondary: Geometric Mean Antibody Concentration (GMC) in 13vPnC Group Relative After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) in 13vPnC Group Relative After the Toddler Dose

End point description:

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

End point type	Secondary

End point timeframe:

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

End point values	13vPnC - Polysorbate 80 After Toddler Dose	13vPnC+Polysorbate 80 After Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	227	238		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=226,238)	13.2 (4.65 to 5.92)	5.38 (4.78 to 6.07)		
Common Serotypes - Serotype 6B (n=225,237)	5.25 (8.7 to 11.23)	10.65 (9.4 to 12.06)		
Common Serotypes - Serotype 9V (n=226,238)	9.89 (2.73 to 3.31)	3.1 (2.8 to 3.42)		
Common Serotypes - Serotype 14 (n=226,238)	3.01 (10.26 to 13.4)	11.95 (10.42 to 13.71)		
Common Serotypes - Serotype 18C (n=226,238)	11.72 (3.06 to 3.78)	3.1 (2.79 to 3.45)		
Common Serotypes - Serotype 19F (n=226,238)	3.4 (8.45 to 10.97)	10.27 (8.99 to 11.73)		
Common Serotypes - Serotype 23F (n=226,238)	9.63 (3.44 to 4.38)	4.15 (3.73 to 4.62)		
Additional Serotypes - Serotype 1 (n=226,238)	3.88 (5.36 to 6.78)	6.11 (5.43 to 6.87)		
Additional Serotypes - Serotype 3 (n=223,236)	6.03 (0.99 to 1.2)	1.16 (1.05 to 1.29)		
Additional Serotypes - Serotype 5 (n=226,238)	1.09 (3.41 to 4.23)	3.98 (3.59 to 4.41)		
Additional Serotypes - Serotype 6A (n=226,237)	3.8 (6.66 to 8.4)	8.19 (7.38 to 9.09)		
Additional Serotypes - Serotype 7F (n=226,238)	7.48 (4.89 to 5.88)	4.95 (4.5 to 5.44)		
Additional Serotypes - Serotype 19A (n=226,238)	5.36 (11.88 to 14.67)	13.02 (11.88 to 14.27)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percent of Subjects Reporting Pre-Specified Local Reactions

End point title	Percent of Subjects Reporting Pre-Specified Local Reactions

End point description:

Local reactions were collected using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (Sig) (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (Mod) (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine, (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Other pre-specified

End point timeframe:

Within 4-days after each dose

End point values	13vPnC + P80 Dose 1 Infant Series	13vPnC - P 80 Dose 1 Infant Series	13vPnC + P80 Dose 2 Infant Series	13vPnC - P80 Dose 2 Infant Series
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	250	250	246	249
Units: percentage of subjects				
number (not applicable)				
Tenderness-Any (n=238,237,228,229,210,216,178,188)	27.7	32.9	26.8	32.8
Tenderness-Sig (n=235,233,220,221,203,211,160,165)	2.1	4.3	0.9	0.5
Swelling-Any (n=236,239,228,228,210,225,174,181)	22.9	30.5	25	36.4
Swelling-Mild (n=236,236,227,226,209,221,169,178)	18.2	24.2	20.3	31.9
Swelling-Mod (n=236,236,224,224,208,217,164,171)	11.9	14.4	11.2	14.3
Swelling-Severe(n=235,233,220,221,203,211,15	0	0	0	0
Redness-Any (n=238,238,232,231,216,226,178,200)	29.8	39.5	38.8	48.5
Redness-Mild (n=238,235,232,230,215,226,176,194)	28.2	35.7	38.4	47
Redness-Mod (n=235,232,220,222,206,211,164,173)	2.1	4.3	1.4	3.2
Redness-Severe (n=235,231,220,221,203,211,159,164)	0	0	0	0

End point values	13vPnC + P80 Dose 3 Infant Series	13vPnC - P80 Dose 3 Infant Series	13vPnC + P80 Toddler Dose	13vPnC - P80 Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	246	247	240	244
Units: percentage of subjects				
number (not applicable)				
Tenderness-Any (n=238,237,228,229,210,216,178,188)	24.8	23.1	42.1	43.1
Tenderness-Sig (n=235,233,220,221,203,211,160,165)	1.5	1.9	2.5	1.2
Swelling-Any (n=236,239,228,228,210,225,174,181)	36.7	38.2	29.9	34.8
Swelling-Mild (n=236,236,227,226,209,221,169,178)	32.5	33.5	26.6	29.8
Swelling-Mod (n=236,236,224,224,208,217,164,171)	13.9	17.5	12.2	19.9
Swelling-Severe(n=235,233,220,221,203,211,15	0	0	0	0
Redness-Any (n=238,238,232,231,216,226,178,200)	46.8	50	42.1	52
Redness-Mild (n=238,235,232,230,215,226,176,194)	46.5	46.9	35.8	46.4
Redness-Mod (n=235,232,220,222,206,211,164,173)	3.9	9	12.8	19.7
Redness-Severe (n=235,231,220,221,203,211,159,164)	0	0	0	0.6

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events

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

End point description:

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

End point type	Other pre-specified

End point timeframe:

Within 4-days after each dose

End point values	13vPnC + P80 Dose 1 Infant Series	13vPnC - P 80 Dose 1 Infant Series	13vPnC + P80 Dose 2 Infant Series	13vPnC - P80 Dose 2 Infant Series
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	250	250	246	249
Units: percentage of subjects				
number (not applicable)				
Fv ≥38°C, ≤39°C(n=236,235,224,229,208,218,17	14	16.2	18.3	17
Fv >39°C, ≤40°C(n=235,233,221,221,203,211,16	0.4	0.4	0.9	0.5
Fv >40°C (n=235,233,221,221,203,211,160,164)	0	0	0	0
Decr appetite (n=237,237,221,224,210,222,172,183)	21.5	22.4	16.3	24.1
Irritability (n=240,239,232,232,215,226,184,198)	55	55.2	51.7	53.9
Incr sleep (n=242,242,231,229,209,221,174,182)	46.3	52.5	35.9	39.3
Decr sleep (n=238,236,227,227,209,217,170,180)	35.7	29.7	24.7	26.4
Meds-treat sx (n=236,235,222,226,205,218,172,168)	14	16.6	15.3	16.8
Meds-prevent sx(n=235,234,220,223,205,217,171,17	14.5	15.8	16.4	15.2

End point values	13vPnC + P80 Dose 3 Infant Series	13vPnC - P80 Dose 3 Infant Series	13vPnC + P80 Toddler Dose	13vPnC - P80 Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	246	247	240	244
Units: percentage of subjects				
number (not applicable)				
Fv ≥38°C, ≤39°C(n=236,235,224,229,208,218,17	19.7	20.6	22.9	18
Fv >39°C, ≤40°C(n=235,233,221,221,203,211,16	1	0.9	2.5	1.8
Fv >40°C (n=235,233,221,221,203,211,160,164)	0	0	0	0
Decr appetite (n=237,237,221,224,210,222,172,183)	21.4	20.7	26.2	29
Irritability (n=240,239,232,232,215,226,184,198)	45.6	50	49.5	56.1
Incr sleep (n=242,242,231,229,209,221,174,182)	25.8	27.6	19	30.8
Decr sleep (n=238,236,227,227,209,217,170,180)	25.4	24.4	19.4	25.6
Meds-treat sx (n=236,235,222,226,205,218,172,168)	15.1	14.7	21.5	15.5
Meds-prevent sx(n=235,234,220,223,205,217,171,17	15.1	10.6	18.7	15.2

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 6 months after the last administration of study drug

Adverse event reporting additional description:

EU BR specific AE tables were
generated separately as per EU format. Latest coding dictionary has been used for EU BR tables.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	13vPnC + P80 Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

Reporting group title	13vPnC - P 80 Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

Reporting group title	13vPnC + P80 Post-Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

Reporting group title	13vPnC - P80 Post-Infant Series

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses).

Reporting group title	13vPnC - P80 Toddler Dose

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Priorix at 12 months of age (toddler dose).

Reporting group title	13vPnC + P80 Toddler Dose

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Priorix at 12 months of age (toddler dose).

Reporting group title	13vPnC + P80 6-Month Follow-up

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC + P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses), and Priorix at 12 months of age (toddler dose).

Reporting group title	13vPnC - P80 6-Month Follow-up

Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC - P80 coadministered with Pentaxim and Engerix-B at 2 months of age, Pentaxim at 3 and 4 months age (infant doses), and Priorix at 12 months of age (toddler dose).

Serious adverse events	13vPnC + P80 Infant Series	13vPnC - P 80 Infant Series	13vPnC + P80 Post-Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 249 (6.02%)	21 / 250 (8.40%)	24 / 249 (9.64%)
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)			
Renal neoplasm			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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			
Fibrosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Immune system disorders			
Alloimmunisation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (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			
Bronchospasm			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (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
Sleep apnoea syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Ultrasound kidney abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Head injury			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	2 / 249 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Limbic traumatic amputation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Radius fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Thermal burn			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Balance disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Leukocytosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	2 / 250 (0.80%)	4 / 249 (1.61%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Hepatobiliary disorders			
Hepatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
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			
Urticaria			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Hydronephrosis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Hypercalciuria			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 249 (1.61%)	9 / 250 (3.60%)	5 / 249 (2.01%)
occurrences causally related to treatment / all	0 / 4	1 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	3 / 250 (1.20%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	1 / 250 (0.40%)	4 / 249 (1.61%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Infectious mononucleosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis meningococcal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Meningococcal sepsis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pharyngitis alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	2 / 249 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia alternative assessment type: Systematic			
subjects affected / exposed	8 / 249 (3.21%)	3 / 250 (1.20%)	6 / 249 (2.41%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia primary atypical alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (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
Respiratory tract infection alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (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
Rhinitis alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	2 / 250 (0.80%)	0 / 249 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (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
Staphylococcal bacteraemia alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	2 / 249 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC - P80 Post-Infant Series	13vPnC - P80 Toddler Dose	13vPnC + P80 Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 250 (6.40%)	2 / 244 (0.82%)	3 / 239 (1.26%)
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)			
Renal neoplasm			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
Fibrosis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (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
Immune system disorders			
Alloimmunisation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Hypersensitivity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Sleep apnoea syndrome			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Investigations			
Ultrasound kidney abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Head injury			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Limbic traumatic amputation			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (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
Radius fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Thermal burn			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
Balance disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Leukocytosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Splenomegaly			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 250 (1.20%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Gastritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	0 / 239 (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
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
Urticaria			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Hydronephrosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Hypercalciuria			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (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			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	1 / 244 (0.41%)	0 / 239 (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
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 250 (1.20%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Infectious mononucleosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
alternative assessment type: Systematic			

subjects affected / exposed	2 / 250 (0.80%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis meningococcal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Meningococcal sepsis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia primary atypical			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (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			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Staphylococcal bacteraemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (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
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 250 (0.80%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC + P80 6-Month Follow-up	13vPnC - P80 6-Month Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 249 (5.22%)	14 / 250 (5.60%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Renal neoplasm			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Fibrosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Alloimmunisation			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Breath holding			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ultrasound kidney abnormal			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Head injury			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limbic traumatic amputation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Balance disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 249 (1.20%)	4 / 250 (1.60%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, obstructive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Urticaria			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Calculus urinary			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalciuria			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	2 / 250 (0.80%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious mononucleosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 249 (1.20%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis meningococcal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningococcal sepsis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nasopharyngitis				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Otitis media				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pharyngitis				
alternative assessment type: Systematic				
subjects affected / exposed	2 / 249 (0.80%)	0 / 250 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pneumonia				
alternative assessment type: Systematic				
subjects affected / exposed	3 / 249 (1.20%)	3 / 250 (1.20%)		
occurrences causally related to treatment / all	0 / 3	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pneumonia primary atypical				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Respiratory tract infection				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Rhinitis				
alternative assessment type: Systematic				

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	13vPnC + P80 Infant Series	13vPnC - P 80 Infant Series	13vPnC + P80 Post-Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	132 / 249 (53.01%)	132 / 250 (52.80%)	15 / 249 (6.02%)
General disorders and administration site conditions			
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 249 (2.01%)	4 / 250 (1.60%)	0 / 249 (0.00%)
occurrences (all)	5	4	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	1	1	0
Injection site induration			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	2	0	0
Injection site nodule			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	2	0	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Fever ≥38°C but ≤39°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	33 / 236 (13.98%)	38 / 235 (16.17%)	0 / 1 (0.00%)
occurrences (all)	33	38	0
Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[2]	41 / 224 (18.30%)	39 / 229 (17.03%)	0 / 1 (0.00%)
occurrences (all)	41	39	0
Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[3]	41 / 208 (19.71%)	45 / 218 (20.64%)	0 / 1 (0.00%)
occurrences (all)	41	45	0
Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[4]	1 / 235 (0.43%)	1 / 233 (0.43%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[5]	2 / 221 (0.90%)	1 / 221 (0.45%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[6]	2 / 203 (0.99%)	2 / 211 (0.95%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[7]	51 / 237 (21.52%)	53 / 237 (22.36%)	0 / 1 (0.00%)
occurrences (all)	51	53	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	36 / 221 (16.29%) 36	54 / 224 (24.11%) 54	0 / 1 (0.00%) 0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	45 / 210 (21.43%) 45	46 / 222 (20.72%) 46	0 / 1 (0.00%) 0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	85 / 238 (35.71%) 85	70 / 236 (29.66%) 70	0 / 1 (0.00%) 0
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	56 / 227 (24.67%) 56	60 / 227 (26.43%) 60	0 / 1 (0.00%) 0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	53 / 209 (25.36%) 53	53 / 217 (24.42%) 53	0 / 1 (0.00%) 0
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[13]	112 / 242 (46.28%)	127 / 242 (52.48%)	0 / 1 (0.00%)
occurrences (all)	112	127	0
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[14]	83 / 231 (35.93%)	90 / 229 (39.30%)	0 / 1 (0.00%)
occurrences (all)	83	90	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[15]	54 / 209 (25.84%)	61 / 221 (27.60%)	0 / 1 (0.00%)
occurrences (all)	54	61	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[16]	132 / 240 (55.00%)	132 / 239 (55.23%)	0 / 1 (0.00%)
occurrences (all)	132	132	0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[17]	120 / 232 (51.72%)	125 / 232 (53.88%)	0 / 1 (0.00%)
occurrences (all)	120	125	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[18]	98 / 215 (45.58%)	113 / 226 (50.00%)	0 / 1 (0.00%)
occurrences (all)	98	113	0
Immune system disorders			

Food allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	3 / 250 (1.20%)	0 / 249 (0.00%)
occurrences (all)	0	3	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	2	0	0
Interstitial lung disease			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	2	0	0
Pharyngolaryngeal pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences (all)	1	0	1
Psychiatric disorders			
Decreased activity			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Insomnia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Investigations			
Cardiac murmur functional			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	2 / 250 (0.80%)	0 / 249 (0.00%)
occurrences (all)	1	2	0

Cardiac murmur			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis congenital			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Brachycephaly			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Cryptorchism			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	1 / 249 (0.40%)
occurrences (all)	0	0	1
Ventricular septal defect			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Aortic valve incompetence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Hypertonia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	3 / 250 (1.20%)	0 / 249 (0.00%)
occurrences (all)	1	3	0
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	2 / 250 (0.80%)	0 / 249 (0.00%)
occurrences (all)	2	2	0
Iron deficiency anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 249 (2.01%)	2 / 250 (0.80%)	1 / 249 (0.40%)
occurrences (all)	5	2	1
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 249 (2.01%)	11 / 250 (4.40%)	0 / 249 (0.00%)
occurrences (all)	5	12	0
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	3 / 250 (1.20%)	0 / 249 (0.00%)
occurrences (all)	3	4	0
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	2 / 250 (0.80%)	0 / 249 (0.00%)
occurrences (all)	1	2	0
Haematochezia			

alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Constipation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	2	0
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Infantile colic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Umbilical hernia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	2 / 249 (0.80%)
occurrences (all)	0	0	2
Stomatitis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	14 / 249 (5.62%)	7 / 250 (2.80%)	3 / 249 (1.20%)
occurrences (all)	14	7	3
Dermatitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 249 (1.20%)	8 / 250 (3.20%)	1 / 249 (0.40%)
occurrences (all)	4	8	1
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 249 (2.01%)	1 / 250 (0.40%)	1 / 249 (0.40%)
occurrences (all)	5	1	1
Dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	1	1	0
Dermatitis diaper			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	1 / 249 (0.40%)
occurrences (all)	1	1	1
Heat rash			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	2	0	0
Dermatitis contact			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Skin inflammation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Urticaria			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Tenderness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	45 / 181 (24.86%)	59 / 181 (32.60%)	0 / 1 (0.00%)
occurrences (all)	45	59	0
Tenderness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	43 / 176 (24.43%)	63 / 176 (35.80%)	0 / 1 (0.00%)
occurrences (all)	43	63	0
Tenderness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	41 / 167 (24.55%)	38 / 170 (22.35%)	0 / 1 (0.00%)
occurrences (all)	41	38	0
Tenderness (significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[22] occurrences (all)	4 / 179 (2.23%) 4	8 / 178 (4.49%) 8	0 / 1 (0.00%) 0
Tenderness (significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	1 / 172 (0.58%) 1	1 / 170 (0.59%) 1	0 / 1 (0.00%) 0
Tenderness (significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	2 / 163 (1.23%) 2	2 / 165 (1.21%) 2	0 / 1 (0.00%) 0
Induration (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	39 / 179 (21.79%) 39	55 / 183 (30.05%) 55	0 / 1 (0.00%) 0
Induration (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[26] occurrences (all)	46 / 178 (25.84%) 46	62 / 175 (35.43%) 62	0 / 1 (0.00%) 0
Induration (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[27]	59 / 165 (35.76%)	67 / 175 (38.29%)	0 / 1 (0.00%)
occurrences (all)	59	67	0
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	33 / 179 (18.44%)	41 / 180 (22.78%)	0 / 1 (0.00%)
occurrences (all)	33	41	0
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	37 / 177 (20.90%)	54 / 173 (31.21%)	0 / 1 (0.00%)
occurrences (all)	37	54	0
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	51 / 165 (30.91%)	56 / 171 (32.75%)	0 / 1 (0.00%)
occurrences (all)	51	56	0
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	18 / 179 (10.06%)	28 / 182 (15.38%)	0 / 1 (0.00%)
occurrences (all)	18	28	0
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	22 / 175 (12.57%)	24 / 172 (13.95%)	0 / 1 (0.00%)
occurrences (all)	22	24	0
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[33] occurrences (all)	23 / 164 (14.02%) 23	30 / 169 (17.75%) 30	0 / 1 (0.00%) 0
Erythema (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[34] occurrences (all)	58 / 181 (32.04%) 58	73 / 183 (39.89%) 73	0 / 1 (0.00%) 0
Erythema (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[35] occurrences (all)	68 / 180 (37.78%) 68	86 / 178 (48.31%) 86	0 / 1 (0.00%) 0
Erythema (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[36] occurrences (all)	78 / 169 (46.15%) 78	89 / 177 (50.28%) 89	0 / 1 (0.00%) 0
Erythema (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	56 / 181 (30.94%) 56	63 / 180 (35.00%) 63	0 / 1 (0.00%) 0
Erythema (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[38]	68 / 180 (37.78%)	82 / 177 (46.33%)	0 / 1 (0.00%)
occurrences (all)	68	82	0
Erythema (Mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	78 / 169 (46.15%)	82 / 177 (46.33%)	0 / 1 (0.00%)
occurrences (all)	78	82	0
Erythema (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	3 / 179 (1.68%)	10 / 178 (5.62%)	0 / 1 (0.00%)
occurrences (all)	3	10	0
Erythema (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	2 / 172 (1.16%)	6 / 171 (3.51%)	0 / 1 (0.00%)
occurrences (all)	2	6	0
Erythema (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	5 / 164 (3.05%)	16 / 165 (9.70%)	0 / 1 (0.00%)
occurrences (all)	5	16	0
Erythema (Severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 179 (0.00%)	0 / 177 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	23 / 249 (9.24%)	19 / 250 (7.60%)	0 / 249 (0.00%)
occurrences (all)	24	19	0
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	19 / 249 (7.63%)	21 / 250 (8.40%)	3 / 249 (1.20%)
occurrences (all)	25	22	3
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 249 (6.83%)	15 / 250 (6.00%)	0 / 249 (0.00%)
occurrences (all)	18	17	0
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 249 (6.83%)	13 / 250 (5.20%)	0 / 249 (0.00%)
occurrences (all)	19	14	0
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 249 (5.22%)	13 / 250 (5.20%)	1 / 249 (0.40%)
occurrences (all)	16	14	1
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 249 (3.21%)	6 / 250 (2.40%)	0 / 249 (0.00%)
occurrences (all)	9	7	0
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 249 (2.81%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	7	1	0
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	3 / 250 (1.20%)	0 / 249 (0.00%)
occurrences (all)	2	3	0
Pneumonia			
alternative assessment type: Systematic			

subjects affected / exposed	3 / 249 (1.20%)	2 / 250 (0.80%)	0 / 249 (0.00%)
occurrences (all)	3	2	0
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	3 / 250 (1.20%)	0 / 249 (0.00%)
occurrences (all)	2	3	0
Ear infection			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	2 / 250 (0.80%)	0 / 249 (0.00%)
occurrences (all)	2	2	0
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 249 (1.20%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	3	1	0
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	2	1	0
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 249 (0.80%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	2	1	0
Exanthema subitum			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	1	1	0
Viral upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	1	1	0
Candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0

Conjunctivitis infective			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis staphylococcal			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Perianal abscess			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Pneumonia primary atypical			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Tinea cruris			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Varicella			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Viral diarrhoea			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	0 / 249 (0.00%)
occurrences (all)	0	1	0
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 249 (0.40%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Influenza			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Weight gain poor			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	0 / 249 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC - P80 Post-Infant Series	13vPnC - P80 Toddler Dose	13vPnC + P80 Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 250 (3.60%)	111 / 244 (45.49%)	91 / 239 (38.08%)
General disorders and administration site conditions			
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Irritability			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 1 (0.00%)	31 / 172 (18.02%)	39 / 170 (22.94%)
occurrences (all)	0	31	39
Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[4] occurrences (all)	0 / 1 (0.00%) 0	3 / 164 (1.83%) 3	4 / 162 (2.47%) 4
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[6] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	0 / 1 (0.00%) 0	53 / 183 (28.96%) 53	45 / 172 (26.16%) 45
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[9]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 1 (0.00%)	46 / 180 (25.56%)	33 / 170 (19.41%)
occurrences (all)	0	46	33
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 1 (0.00%)	56 / 182 (30.77%)	33 / 174 (18.97%)
occurrences (all)	0	56	33
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 1 (0.00%)	111 / 198 (56.06%)	91 / 184 (49.46%)
occurrences (all)	0	111	91
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Decreased activity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Insomnia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur functional			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis congenital			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Brachycephaly			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Cryptorchism			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Ventricular septal defect			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Aortic valve incompetence			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Tricuspid valve incompetence			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Hypertonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	3 / 244 (1.23%)	0 / 239 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	5 / 244 (2.05%)	4 / 239 (1.67%)
occurrences (all)	0	5	4
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	2
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Infantile colic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	1 / 244 (0.41%)	2 / 239 (0.84%)
occurrences (all)	1	1	2
Dermatitis allergic			
alternative assessment type: Systematic			

subjects affected / exposed	2 / 250 (0.80%)	1 / 244 (0.41%)	0 / 239 (0.00%)
occurrences (all)	2	1	0
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Heat rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Skin inflammation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Urticaria			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 1 (0.00%)	81 / 188 (43.09%)	75 / 178 (42.13%)
occurrences (all)	0	81	75
Tenderness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tenderness (significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 1 (0.00%)	2 / 165 (1.21%)	4 / 160 (2.50%)
occurrences (all)	0	2	4
Tenderness (significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Tenderness (significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Induration (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 1 (0.00%)	63 / 181 (34.81%)	52 / 174 (29.89%)
occurrences (all)	0	63	52
Induration (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Induration (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 1 (0.00%)	53 / 178 (29.78%)	45 / 169 (26.63%)
occurrences (all)	0	53	45
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[29]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 1 (0.00%)	34 / 171 (19.88%)	20 / 164 (12.20%)
occurrences (all)	0	34	20
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 1 (0.00%)	104 / 200 (52.00%)	75 / 178 (42.13%)
occurrences (all)	0	104	75
Erythema (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[35] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Erythema (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[36] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Erythema (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	0 / 1 (0.00%) 0	90 / 194 (46.39%) 90	63 / 176 (35.80%) 63
Erythema (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Erythema (Mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Erythema (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[40]	0 / 1 (0.00%)	34 / 173 (19.65%)	21 / 164 (12.80%)
occurrences (all)	0	34	21
Erythema (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema (Severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 1 (0.00%)	1 / 164 (0.61%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	6 / 244 (2.46%)	3 / 239 (1.26%)
occurrences (all)	0	6	3
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	10 / 244 (4.10%)	8 / 239 (3.35%)
occurrences (all)	1	11	8
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	19 / 244 (7.79%)	10 / 239 (4.18%)
occurrences (all)	0	19	10
Upper respiratory tract infection			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	17 / 244 (6.97%)	9 / 239 (3.77%)
occurrences (all)	0	19	9
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	10 / 244 (4.10%)	4 / 239 (1.67%)
occurrences (all)	0	10	4
Respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	2 / 239 (0.84%)
occurrences (all)	0	1	2
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Ear infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	3 / 239 (1.26%)
occurrences (all)	0	1	3
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	4 / 244 (1.64%)	1 / 239 (0.42%)
occurrences (all)	0	4	1
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	2 / 244 (0.82%)	1 / 239 (0.42%)
occurrences (all)	0	2	1
Exanthema subitum			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	5 / 244 (2.05%)	0 / 239 (0.00%)
occurrences (all)	0	5	0
Viral upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis staphylococcal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Perianal abscess			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pneumonia primary atypical			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Varicella			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	1 / 244 (0.41%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Viral diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Acute tonsillitis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 250 (0.00%)	2 / 244 (0.82%)	0 / 239 (0.00%)
occurrences (all)	0	2	0
Influenza			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 250 (0.00%)	0 / 244 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Weight gain poor			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 250 (0.40%)	0 / 244 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC + P80 6-Month Follow-up	13vPnC - P80 6-Month Follow-up	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
General disorders and administration site conditions			
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Injection site induration			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Injection site nodule			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Fever ≥38°C but ≤39°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[1]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[2]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[3]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[4]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[5]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[11]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[17] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[18] occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	
Immune system disorders			
Food allergy alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	0 / 250 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Cough alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	0 / 250 (0.00%) 0	
Interstitial lung disease alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	0 / 250 (0.00%) 0	
Pharyngolaryngeal pain alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	0 / 250 (0.00%) 0	
Rhinitis allergic alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	0 / 250 (0.00%) 0	
Psychiatric disorders			

Decreased activity			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Insomnia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Investigations			
Cardiac murmur functional			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Cardiac murmur			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Craniotabes			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Dacryostenosis congenital			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Brachycephaly			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Cryptorchism			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Ventricular septal defect			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Aortic valve incompetence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Tricuspid valve incompetence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Hypertonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Hypotonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctivitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Haematochezia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Aphthous stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Constipation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Infantile colic			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Umbilical hernia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	1 / 250 (0.40%)	
occurrences (all)	0	1	
Dermatitis allergic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Dermatitis diaper			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Heat rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Dermatitis contact			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Skin inflammation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Urticaria			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tenderness (significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tenderness (significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tenderness (significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[25]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[36]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Erythema (Severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Bronchopneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Viral infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Ear infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Laryngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Otitis media			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	

Exanthema subitum			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis infective			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis staphylococcal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Perianal abscess			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Pneumonia primary atypical			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Tinea cruris			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Varicella			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Viral diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Viral rash			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Acute tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Influenza			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 249 (0.00%)	0 / 250 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Weight gain poor			
alternative assessment type: Systematic			

subjects affected / exposed occurrences (all)	0 / 249 (0.00%) 0	0 / 250 (0.00%) 0	

Notes:

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

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

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 July 2006	HBVAXPRO vaccine (not available for purchase) was replaced with Engerix-B vaccine and meningitis C vaccine was allowed to be given 14 days before study vaccination or after the post vaccination observation period.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported