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

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

Summary

EudraCT number	2008-004768-38
Trial protocol	Outside EU/EEA
Global end of trial date	22 September 2009

Results information

Result version number	v2 (current)
This version publication date	29 July 2016
First version publication date	01 August 2015
Version creation reason	• Correction of full data set reporting periods and duplicate AEs in their data

Trial information

Trial identification

Sponsor protocol code	6096A1-012

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00676091
WHO universal trial number (UTN)	-
Other trial identifiers	Alias Number: B1851003

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Clinical Trials.gov Call Center, Pfizer, Inc., 001 800 7181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer, Inc., 001 800 7181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 May 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 September 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the pneumococcal immune responses induced by 13-valent Pneumococcal Conjugate Vaccine (13vPnC) relative to the pneumococcal immune responses induced by 7-valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the infant series.
To assess the immune responses induced by the diphtheria, tetanus, whole cell pertussis, and Haemophilus influenzae type b vaccine (DTP-Hib) given with 13vPnC relative to the immune responses induced by DTP-Hib given with 7vPnC when measured 1 month after the infant series. The following antigens in DTP-Hib were assessed: pertussis antigens (pertussis toxoid [PT], filamentous haemagglutinin [FHA], and pertactin [PRN]).
To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and adverse events (AEs).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Brazil: 354
Worldwide total number of subjects	354
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	354
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 354 were enrolled in the study. Subjects randomized in 13vPnC and 7vPnC arms were 177 and 177, respectively. From the randomized subjects, 163 and 162 subjects were vaccinated with Dose 1 for the respective arms.

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, Subject, Assessor

Arms

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

Arm description:

13vPnC administered intramuscularly at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

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

Arm title	7vPnC- Infant Series

Arm description:

7vPnC administered intramuscularly at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

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

Number of subjects in period 1	13vPnC- Infant Series	7vPnC- Infant Series
Started	177	177
Vaccinated Dose 1	163	162
Vaccinated Dose 2	159	162
Vaccinated Dose 3	158	161
Completed	157	159
Not completed	20	18
Parent or legal guardian request	10	8
Adverse Event	2	3
Failed to return	1	3
Protocol Violation	6	3
Lost to follow-up	1	-
Died prior to receiving 7vPnC	-	1

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

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

Arm description:

13vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series); assessment 1 month after the infant series (7 months of age).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC- After the Infant Series

Arm description:

7vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series); assessment 1 month after the infant series (7 months of age).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC- After the Infant Series	7vPnC- After the Infant Series
Started	157	159
Completed	156	156
Not completed	1	3
Failed to return	1	1
Adverse Event	-	1
Protocol Violation	-	1

Period 3

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC Toddler Dose

Arm description:

13vPnC administered intramuscularly at 12 months of age (toddler dose).

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

Dosage and administration details:

A 0.5 mL dose of 13vPnC was administered intramuscularly at 12 months of age (toddler dose).

Arm title	7vPnC Toddler Dose

Arm description:

7vPnC administered intramuscularly at 12 months of age (toddler dose).

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

Dosage and administration details:

A 0.5 mL dose of 7vPnC was administered intramuscularly at 12 months of age (toddler dose).

Number of subjects in period 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	156	156
Completed	153	156
Not completed	3	0
Parent or legal guardian request	1	-
Failed to return	2	-

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC- Infant Series
Reporting group description:	
13vPnC administered intramuscularly at 2, 4, and 6 months of age (infant series).	
Reporting group title	7vPnC- Infant Series
Reporting group description:	
7vPnC administered intramuscularly at 2, 4, and 6 months of age (infant series).	

Reporting group values	13vPnC- Infant Series	7vPnC- Infant Series	Total
Number of subjects	177	177	354
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	1.2	1.2	
standard deviation	± 0.2	± 0.2	-
Gender categorical Units: Subjects			
Female	99	83	182
Male	78	94	172

End points

End points reporting groups

Reporting group title	13vPnC- Infant Series
Reporting group description:	
13vPnC administered intramuscularly at 2, 4, and 6 months of age (infant series).	
Reporting group title	7vPnC- Infant Series
Reporting group description:	
7vPnC administered intramuscularly at 2, 4, and 6 months of age (infant series).	
Reporting group title	13vPnC- After the Infant Series
Reporting group description:	
13vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series); assessment 1 month after the infant series (7 months of age).	
Reporting group title	7vPnC- After the Infant Series
Reporting group description:	
7vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series); assessment 1 month after the infant series (7 months of age).	
Reporting group title	13vPnC Toddler Dose
Reporting group description:	
13vPnC administered intramuscularly at 12 months of age (toddler dose).	
Reporting group title	7vPnC Toddler Dose
Reporting group description:	
7vPnC administered intramuscularly at 12 months of age (toddler dose).	

Primary: Percentage of Subjects Achieving Serotype Specific immunoglobulin G (IgG) Antibody Concentration ≥0.35 Micrograms Per Milliliter (mcg/mL) in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Serotype Specific immunoglobulin G (IgG) Antibody Concentration ≥0.35 Micrograms Per Milliliter (mcg/mL) in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series[1]

End point description:

Percentage of subjects achieving predefined antibody threshold greater than or equal to (≥)0.35 mcg/mL along with the corresponding 95% 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) are presented. Evaluable immunogenicity population: treatments as randomized at all expected doses, blood drawn within specified timeframes, at least 1 valid and determinate assay result for proposed analysis, and no major protocol violations.

End point type	Primary

End point timeframe:

1 Month after the infant series (7 Months of age)

Notes:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156[2]	158[3]		
Units: percentage of subjects				
number (confidence interval 95%)				
Common serotypes - serotype 4	100 (97.7 to 100)	100 (97.7 to 100)		
Common serotypes - serotype 6B	96.8 (92.7 to 99)	95.6 (91.1 to 98.2)		
Common serotypes - serotype 9V	98.7 (95.4 to 99.8)	100 (97.7 to 100)		
Common serotypes - serotype 14	98.1 (94.5 to 99.6)	97.5 (93.6 to 99.3)		
Common serotypes - serotype 18C	97.4 (93.6 to 99.3)	98.1 (94.5 to 99.6)		
Common serotypes - serotype 19F	94.2 (89.3 to 97.3)	98.7 (95.5 to 99.8)		
Common serotypes - serotype 23F	96.8 (92.7 to 99)	93 (87.8 to 96.5)		
Additional serotypes - serotype 1	99.4 (96.5 to 100)	2.5 (0.7 to 6.4)		
Additional serotypes - serotype 3	87.1 (80.8 to 91.9)	4.4 (1.8 to 8.9)		
Additional serotypes - serotype 5	98.7 (95.4 to 99.8)	38.2 (30.4 to 46.4)		
Additional serotypes - serotype 6A	97.4 (93.6 to 99.3)	52.6 (44.4 to 60.6)		
Additional serotypes - serotype 7F	100 (97.7 to 100)	1.3 (0.2 to 4.6)		
Additional serotypes - serotype 19A	99.4 (96.5 to 100)	98.7 (95.4 to 99.8)		

Notes:

[2] - Number of subjects with a determinate IgG antibody concentration to the given serotype.

[3] - Number of subjects with a determinate IgG antibody concentration to the given serotype.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving Antibody Level ≥5 Enzyme-linked Immunosorbent Assay (ELISA) Units Per mL (EU/mL) for Pertussis in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Antibody Level ≥5 Enzyme-linked Immunosorbent Assay (ELISA) Units Per mL (EU/mL) for Pertussis in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series[4]

End point description:

Percentage of subjects achieving predefined antibody threshold ≥5 EU/mL along with the corresponding 95% CI for concomitant antigen pertussis (PT, FHA, and PRN) are presented. Evaluable immunogenicity population.

End point type	Primary

End point timeframe:

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

Notes:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156[5]	158[6]		
Units: percentage of subjects				
number (confidence interval 95%)				
PT ≥5 EU/mL	35.9 (28.4 to 44)	32.3 (25.1 to 40.2)		
FHA ≥5 EU/mL	70.1 (62.2 to 77.2)	71.5 (63.8 to 78.4)		
PRN ≥5 EU/mL	93.5 (88.5 to 96.9)	96.2 (91.9 to 98.6)		

Notes:

[5] - Number of subjects with a determinate antibody concentration to given concomitant vaccine component.
[6] - Number of subjects with a determinate antibody concentration to given concomitant vaccine component.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serotype Specific IgG Antibody Concentration ≥0.35 mcg/mL in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Serotype Specific IgG Antibody Concentration ≥0.35 mcg/mL in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving predefined antibody threshold ≥0.35 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity population.

End point type	Secondary

End point timeframe:

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

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152[7]	152[8]		
Units: percentage of subjects				
number (confidence interval 95%)				
Common serotypes - serotype 4	100 (97.6 to 100)	100 (97.6 to 100)		
Common serotypes - serotype 6B	97.4 (93.4 to 99.3)	98.7 (95.3 to 99.8)		
Common serotypes - serotype 9V	100 (97.6 to 100)	100 (97.6 to 100)		
Common serotypes - serotype 14	100 (97.6 to 100)	99.3 (96.4 to 100)		
Common serotypes - serotype 18C	99.3 (96.4 to 100)	100 (97.6 to 100)		
Common serotypes - serotype 19F	99.3 (96.4 to 100)	98.7 (95.3 to 99.8)		

Common serotypes - serotype 23F	98.7 (95.3 to 100)	99.3 (96.4 to 100)		
Additional serotypes - serotype 1	100 (97.6 to 100)	2.7 (0.7 to 6.7)		
Additional serotypes - serotype 3	92.1 (86.5 to 95.8)	7.5 (3.8 to 13)		
Additional serotypes - serotype 5	100 (97.6 to 100)	72.1 (63.9 to 79.4)		
Additional serotypes - serotype 6A	100 (97.6 to 100)	72.1 (63.9 to 79.4)		
Additional serotypes - serotype 7F	100 (97.6 to 100)	4.2 (1.5 to 8.8)		
Additional serotypes - serotype 19A	100 (97.6 to 100)	100 (97.6 to 100)		

Notes:

[7] - Number of subjects with a determinate IgG antibody concentration to the given serotype.

[8] - Number of subjects with a determinate IgG antibody concentration to the given serotype.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Antibody Level ≥5 EU/mL for Pertussis in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Antibody Level ≥5 EU/mL for Pertussis in the 13vPnC Group Relative to 7vPnC Group 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving predefined antibody threshold ≥5 EU/mL along with the corresponding 95% CI for concomitant antigen pertussis (PT, FHA, and PRN) are presented. Evaluable immunogenicity population.

End point type	Secondary

End point timeframe:

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

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152[9]	152[10]		
Units: percentage of subjects				
number (confidence interval 95%)				
PT ≥5 EU/mL	50.7 (42.4 to 58.9)	49.3 (41.1 to 57.6)		
FHA ≥5 EU/mL	91.4 (85.8 to 95.4)	88.8 (82.7 to 93.3)		
PRN ≥5 EU/mL	99.3 (96.4 to 100)	98.7 (95.3 to 99.8)		

Notes:

[9] - Number of subjects with a determinate antibody concentration to given concomitant vaccine component.

[10] - Number of subjects with a determinate antibody concentration to given concomitant vaccine component.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145[11]	156[12]		
Units: percentage of subejcts				
number (not applicable)				
Tenderness: Any	60	59.4		
Tenderness: Significant	14	12.8		
Swelling: Any	13.9	15		
Swelling: Mild	10.3	13.6		
Swelling: Moderate	5.9	1.4		
Swelling: Severe	0	0		
Redness: Any	10.3	13.4		
Redness: Mild	8.8	11.4		
Redness: Moderate	2.9	2.1		
Redness: Severe	0	0		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	137[13]	145[14]		
Units: percentage of subejcts				
number (not applicable)				
Tenderness: Any	53.3	53.8		
Tenderness: Significant	9.4	11.9		
Swelling: Any	12.1	13.8		
Swelling: Mild	10.5	10		
Swelling: Moderate	2.4	3.9		
Swelling: Severe	0	0		
Redness: Any	9.3	12.4		
Redness: Mild	9.3	11.6		
Redness: Moderate	0	1.6		
Redness: Severe	0	0		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134[15]	134[16]		
Units: percentage of subejcts				
number (not applicable)				
Tenderness: Any	48.1	47.4		
Tenderness: Significant	10.9	8.8		

Swelling: Any	14.6	9.7		
Swelling: Mild	12.2	9.7		
Swelling: Moderate	4.2	0.9		
Swelling: Severe	0	0		
Redness: Any	10.7	14		
Redness: Mild	10.7	13.3		
Redness: Moderate	0.8	0.9		
Redness: Severe	0	0		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128[17]	128[18]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any	64.3	53.2		
Tenderness: Significant	18.3	13.3		
Swelling: Any	11.5	10.5		
Swelling: Mild	8.1	8.7		
Swelling: Moderate	5.3	3.9		
Swelling: Severe	0	0		
Redness: Any	13.3	8.7		
Redness: Mild	12.4	7.8		
Redness: Moderate	0.9	1		
Redness: Severe	0	0		

Notes:

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

[18] - Number of subjects reporting yes for at least 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Pre-specified systemic events (any fever ≥ 38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received at least 1 dose of study vaccine.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	154[19]	154[20]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C	18	19.9		
Fever>39 but less than or equal to(≤)40 degrees C	0	0.7		
Fever >40 degrees C	0	0		
Decreased appetite	26.6	28		
Irritability	80.3	77.9		
Increased sleep	56.6	52.4		
Decreased sleep	39.7	27.5		

Notes:

[19] - Number of subjects reporting yes for at least 1 day or no for all days.

[20] - Number of subjects reporting yes for at least 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Pre-specified systemic events (any fever ≥ 38 degrees C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received at least 1 dose of study vaccine.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141[21]	157[22]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C	23.8	23		
Fever >39 but ≤40 degrees C	3.2	0.8		
Fever >40 degrees C	0	0		
Decreased appetite	33.8	29.6		
Irritability	80.4	79.2		
Increased sleep	32.8	38.7		
Decreased sleep	25.8	36		

Notes:

[21] - Number of subjects reporting yes for at least 1 day or no for all days.

[22] - Number of subjects reporting yes for at least 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Pre-specified systemic events (any fever ≥ 38 degrees Celsius C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received at least 1 dose of study vaccine.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC- Infant Series	7vPnC- Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	148[23]	144[24]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C	22.6	22.4		
Fever >39 but ≤40 degrees C	4.2	3.5		
Fever >40 degrees C	0.8	0.9		
Decreased appetite	37.9	32.2		
Irritability	76.9	71.2		
Increased sleep	35.7	36.9		
Decreased sleep	27.6	34.1		

Notes:

[23] - Number of subjects reporting yes for at least 1 day or no for all days.

[24] - Number of subjects reporting yes for at least 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Pre-specified systemic events (any fever ≥ 38 degrees Celsius C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received at least 1 dose of study vaccine.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132[25]	133[26]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C	31	29.9		
Fever >39 but ≤40 degrees C	1.8	3		
Fever >40 degrees C	0.9	0		
Decreased appetite	33.3	39		
Irritability	67.2	68.8		
Increased sleep	30.8	24.1		
Decreased sleep	22.7	20.6		

Notes:

[25] - Number of subjects reporting yes for at least 1 day or no for all days.

[26] - Number of subjects reporting yes for at least 1 day or no for all days.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were reported from signing of informed consent form (ICF) to 28 to 56 days after third dose of infant series & from toddler dose to 28 to 56 days after toddler dose.SAEs were reported from signing of the ICF to 1 month after the last study vaccination

Adverse event reporting additional description:

Safety population.AE may be reported as both a serious & non-serious, but are distinct events. AE =serious for 1 subject & =non-serious for other subject/ subject may have experienced both serious & non-serious episode of same event.Version was not captured, 0.0 is mentioned for dictionary version. LRs,SEs assessed for Infant & toddler groups only.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC Infant Series

Reporting group description:

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

Reporting group title	7vPnC Infant Series

Reporting group description:

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

Reporting group title	After the Infant Series 13vPnC

Reporting group description:

13vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series); assessment between 1 month after infant series and toddler dose.

Reporting group title	After the Infant Series 7vPnC

Reporting group description:

7vPnC 0.5 mL dose administered intramuscularly at 2, 4, and 6 months of age (infant series); assessment between 1 month after infant series and toddler dose.

Reporting group title	13vPnC Toddler Dose

Reporting group description:

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

Reporting group title	7vPnC Toddler Dose

Reporting group description:

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

Serious adverse events	13vPnC Infant Series	7vPnC Infant Series	After the Infant Series 13vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 163 (6.13%)	10 / 162 (6.17%)	10 / 163 (6.13%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Congenital, familial and genetic disorders			
Congenital hydrocephalus			

subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (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			
Hypotonic-hyporesponsive episode			
subjects affected / exposed	1 / 163 (0.61%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (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
Grand mal convulsion			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
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			
Inguinal hernia			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (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
Umbilical hernia			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (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			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	2 / 163 (1.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	2 / 163 (1.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 163 (0.00%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	1 / 163 (0.61%)
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 viral			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia primary atypical			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (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
Bronchopneumonia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	2 / 163 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis viral			

subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
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			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	After the Infant Series 7vPnC	13vPnC Toddler Dose	7vPnC Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 162 (3.09%)	2 / 155 (1.29%)	3 / 156 (1.92%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Congenital, familial and genetic disorders			
Congenital hydrocephalus			
subjects affected / exposed	1 / 162 (0.62%)	0 / 155 (0.00%)	0 / 156 (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
Nervous system disorders			
Hypotonic-hyporesponsive episode			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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
Convulsion			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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
Grand mal convulsion			

subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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			
Inguinal hernia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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
Umbilical hernia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 162 (0.62%)	1 / 155 (0.65%)	2 / 156 (1.28%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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			

subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (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
Urinary tract infection			
subjects affected / exposed	1 / 162 (0.62%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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 primary atypical			

subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	2 / 162 (1.23%)	0 / 155 (0.00%)	2 / 156 (1.28%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	1 / 162 (0.62%)	0 / 155 (0.00%)	0 / 156 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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
Tracheobronchitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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
Tracheobronchitis viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	13vPnC Infant Series	7vPnC Infant Series	After the Infant Series 13vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	145 / 163 (88.96%)	142 / 162 (87.65%)	8 / 163 (4.91%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hyperaemia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Pallor			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	12 / 163 (7.36%)	8 / 162 (4.94%)	0 / 163 (0.00%)
occurrences (all)	14	8	0
Inflammation			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	4 / 163 (2.45%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	4	2	0
Irritability			
subjects affected / exposed	2 / 163 (1.23%)	4 / 162 (2.47%)	0 / 163 (0.00%)
occurrences (all)	2	4	0
Injection site pain			
subjects affected / exposed	1 / 163 (0.61%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
Tenderness			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	1	1	0

Hypothermia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	2	0
Injection site exfoliation			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Vaccination site reaction			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Injection site scar			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Injection site swelling			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Vaccination site erythema			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (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 SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	25 / 139 (17.99%)	28 / 141 (19.86%)	0 / 163 (0.00%)
occurrences (all)	25	28	0

Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 135 (0.00%)	1 / 138 (0.72%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Fever >40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Sysetmic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 135 (0.00%)	0 / 138 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	38 / 143 (26.57%)	40 / 143 (27.97%)	0 / 163 (0.00%)
occurrences (all)	38	40	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	122 / 152 (80.26%)	116 / 149 (77.85%)	0 / 163 (0.00%)
occurrences (all)	122	116	0
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	81 / 143 (56.64%)	77 / 147 (52.38%)	0 / 163 (0.00%)
occurrences (all)	81	77	0
Decreased sleep: Infant Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	56 / 141 (39.72%)	38 / 138 (27.54%)	0 / 163 (0.00%)
occurrences (all)	56	38	0

Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	31 / 130 (23.85%)	31 / 135 (22.96%)	0 / 163 (0.00%)
occurrences (all)	31	31	0
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	4 / 124 (3.23%)	1 / 128 (0.78%)	0 / 163 (0.00%)
occurrences (all)	4	1	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	44 / 130 (33.85%)	40 / 135 (29.63%)	0 / 163 (0.00%)
occurrences (all)	44	40	0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	111 / 138 (80.43%)	122 / 154 (79.22%)	0 / 163 (0.00%)
occurrences (all)	111	122	0
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	41 / 125 (32.80%)	55 / 142 (38.73%)	0 / 163 (0.00%)
occurrences (all)	41	55	0
Decreased sleep: Infant Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	33 / 128 (25.78%)	49 / 136 (36.03%)	0 / 163 (0.00%)
occurrences (all)	33	49	0

Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	28 / 124 (22.58%)	26 / 116 (22.41%)	0 / 163 (0.00%)
occurrences (all)	28	26	0
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	5 / 119 (4.20%)	4 / 113 (3.54%)	0 / 163 (0.00%)
occurrences (all)	5	4	0
Fever >40°C : Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	1 / 119 (0.84%)	1 / 112 (0.89%)	0 / 163 (0.00%)
occurrences (all)	1	1	0
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	50 / 132 (37.88%)	39 / 121 (32.23%)	0 / 163 (0.00%)
occurrences (all)	50	39	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	110 / 143 (76.92%)	99 / 139 (71.22%)	0 / 163 (0.00%)
occurrences (all)	110	99	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	46 / 129 (35.66%)	45 / 122 (36.89%)	0 / 163 (0.00%)
occurrences (all)	46	45	0

Decreased sleep: Infant Series Dose 3 alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	35 / 127 (27.56%) 35	43 / 126 (34.13%) 43	0 / 163 (0.00%) 0
Immune system disorders			
Allergy to arthropod sting subjects affected / exposed occurrences (all)	2 / 163 (1.23%) 2	5 / 162 (3.09%) 5	0 / 163 (0.00%) 0
Milk allergy subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	1 / 162 (0.62%) 1	1 / 163 (0.61%) 1
Allergy to arthropod bite subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 162 (0.00%) 0	1 / 163 (0.61%) 1
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	8 / 163 (4.91%) 8	12 / 162 (7.41%) 13	0 / 163 (0.00%) 0
Bronchospasm subjects affected / exposed occurrences (all)	4 / 163 (2.45%) 4	5 / 162 (3.09%) 7	0 / 163 (0.00%) 0
Allergic cough subjects affected / exposed occurrences (all)	3 / 163 (1.84%) 3	3 / 162 (1.85%) 3	0 / 163 (0.00%) 0
Asthmatic crisis subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Bronchial hyperreactivity			

subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	1 / 163 (0.61%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	2	0	0
Upper airway obstruction			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	4 / 163 (2.45%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences (all)	4	0	1
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	3 / 163 (1.84%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	3	1	0
Traumatic brain injury			
subjects affected / exposed	1 / 163 (0.61%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	2	1	0
Hydrocele			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Ventricular septal defect			

subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences (all)	0	0	1
Nervous system disorders			
Hypokinesia			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Poor quality sleep			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Psychomotor skills impaired			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 163 (2.45%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	4	3	0
Lymphadenopathy			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	4 / 163 (2.45%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	4	3	0
Lacrimation increased			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	1	1	0

Strabismus			
subjects affected / exposed	0 / 163 (0.00%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	0	2	0
Eye discharge			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	14 / 163 (8.59%)	10 / 162 (6.17%)	0 / 163 (0.00%)
occurrences (all)	14	10	0
Gastrooesophageal reflux disease			
subjects affected / exposed	8 / 163 (4.91%)	9 / 162 (5.56%)	0 / 163 (0.00%)
occurrences (all)	8	9	0
Vomiting			
subjects affected / exposed	9 / 163 (5.52%)	6 / 162 (3.70%)	0 / 163 (0.00%)
occurrences (all)	9	6	0
Abdominal pain			
subjects affected / exposed	9 / 163 (5.52%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	9	3	0
Constipation			
subjects affected / exposed	6 / 163 (3.68%)	4 / 162 (2.47%)	0 / 163 (0.00%)
occurrences (all)	6	4	0
Inguinal hernia			
subjects affected / exposed	1 / 163 (0.61%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	1	3	0
Nausea			
subjects affected / exposed	3 / 163 (1.84%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	3	0	0
Abnormal faeces			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Haematochezia			

subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Oral mucosal discolouration			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Regurgitation			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Umbilical hernia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	7 / 163 (4.29%)	4 / 162 (2.47%)	0 / 163 (0.00%)
occurrences (all)	7	4	0
Dermatitis			
subjects affected / exposed	2 / 163 (1.23%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	2	3	0
Dermatitis contact			
subjects affected / exposed	3 / 163 (1.84%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	3	2	0
Rash			
subjects affected / exposed	2 / 163 (1.23%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	2	3	0
Dermatitis diaper			
subjects affected / exposed	1 / 163 (0.61%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	1	3	0
Dry skin			
subjects affected / exposed	1 / 163 (0.61%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	1	3	0
Dermatitis allergic			
subjects affected / exposed	2 / 163 (1.23%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	2	0	0

Erythema			
subjects affected / exposed	2 / 163 (1.23%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	2	0	0
Pityriasis alba			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Prurigo			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Rash generalised			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Heat rash			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	87 / 145 (60.00%)	92 / 155 (59.35%)	0 / 163 (0.00%)
occurrences (all)	87	92	0
Tenderness (Significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	19 / 136 (13.97%)	18 / 141 (12.77%)	0 / 163 (0.00%)
occurrences (all)	19	18	0
Swelling (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[23]	19 / 137 (13.87%)	21 / 140 (15.00%)	0 / 163 (0.00%)
occurrences (all)	19	21	0
Swelling (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	14 / 136 (10.29%)	19 / 140 (13.57%)	0 / 163 (0.00%)
occurrences (all)	14	19	0
Swelling (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	8 / 136 (5.88%)	2 / 138 (1.45%)	0 / 163 (0.00%)
occurrences (all)	8	2	0
Redness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	14 / 136 (10.29%)	19 / 142 (13.38%)	0 / 163 (0.00%)
occurrences (all)	14	19	0
Redness (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	12 / 136 (8.82%)	16 / 140 (11.43%)	0 / 163 (0.00%)
occurrences (all)	12	16	0
Redness (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	4 / 136 (2.94%)	3 / 140 (2.14%)	0 / 163 (0.00%)
occurrences (all)	4	3	0
Tenderness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[29]	72 / 135 (53.33%)	78 / 145 (53.79%)	0 / 163 (0.00%)
occurrences (all)	72	78	0
Tenderness (Significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	12 / 127 (9.45%)	16 / 134 (11.94%)	0 / 163 (0.00%)
occurrences (all)	12	16	0
Swelling (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	15 / 124 (12.10%)	18 / 130 (13.85%)	0 / 163 (0.00%)
occurrences (all)	15	18	0
Swelling (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	13 / 124 (10.48%)	13 / 130 (10.00%)	0 / 163 (0.00%)
occurrences (all)	13	13	0
Swelling (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	3 / 124 (2.42%)	5 / 128 (3.91%)	0 / 163 (0.00%)
occurrences (all)	3	5	0
Redness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	12 / 129 (9.30%)	16 / 129 (12.40%)	0 / 163 (0.00%)
occurrences (all)	12	16	0
Redness (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[35]	12 / 129 (9.30%)	15 / 129 (11.63%)	0 / 163 (0.00%)
occurrences (all)	12	15	0
Redness (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 123 (0.00%)	2 / 128 (1.56%)	0 / 163 (0.00%)
occurrences (all)	0	2	0
Tenderness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Recations 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	63 / 131 (48.09%)	63 / 133 (47.37%)	0 / 163 (0.00%)
occurrences (all)	63	63	0
Tenderness (Significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	13 / 119 (10.92%)	10 / 114 (8.77%)	0 / 163 (0.00%)
occurrences (all)	13	10	0
Swelling (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	18 / 123 (14.63%)	11 / 113 (9.73%)	0 / 163 (0.00%)
occurrences (all)	18	11	0
Swelling (Mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	15 / 123 (12.20%)	11 / 113 (9.73%)	0 / 163 (0.00%)
occurrences (all)	15	11	0
Swelling (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[41]	5 / 120 (4.17%)	1 / 113 (0.88%)	0 / 163 (0.00%)
occurrences (all)	5	1	0
Redness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	13 / 121 (10.74%)	16 / 114 (14.04%)	0 / 163 (0.00%)
occurrences (all)	13	16	0
Redness (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	1 / 120 (0.83%)	1 / 113 (0.88%)	0 / 163 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Pyelocaliectasis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	3 / 163 (1.84%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	3	2	0
Arthralgia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Joint range of motion decreased			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	54 / 163 (33.13%)	54 / 162 (33.33%)	2 / 163 (1.23%)
occurrences (all)	74	81	2
Nasopharyngitis			
subjects affected / exposed	55 / 163 (33.74%)	43 / 162 (26.54%)	0 / 163 (0.00%)
occurrences (all)	77	66	0

Gastroenteritis			
subjects affected / exposed	10 / 163 (6.13%)	12 / 162 (7.41%)	0 / 163 (0.00%)
occurrences (all)	12	12	0
Perineal infection			
subjects affected / exposed	7 / 163 (4.29%)	9 / 162 (5.56%)	0 / 163 (0.00%)
occurrences (all)	9	9	0
Bronchiolitis			
subjects affected / exposed	9 / 163 (5.52%)	5 / 162 (3.09%)	0 / 163 (0.00%)
occurrences (all)	10	6	0
Oral candidiasis			
subjects affected / exposed	2 / 163 (1.23%)	12 / 162 (7.41%)	0 / 163 (0.00%)
occurrences (all)	3	16	0
Urinary tract infection			
subjects affected / exposed	5 / 163 (3.07%)	4 / 162 (2.47%)	0 / 163 (0.00%)
occurrences (all)	7	6	0
Ear infection			
subjects affected / exposed	5 / 163 (3.07%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	5	2	0
Varicella			
subjects affected / exposed	6 / 163 (3.68%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	6	1	0
Exanthema subitum			
subjects affected / exposed	3 / 163 (1.84%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	3	3	0
Influenza			
subjects affected / exposed	3 / 163 (1.84%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	3	3	0
Otitis media			
subjects affected / exposed	3 / 163 (1.84%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	3	4	0
Tracheobronchitis			
subjects affected / exposed	3 / 163 (1.84%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	3	3	0
Viral rash			
subjects affected / exposed	2 / 163 (1.23%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	2	3	0

Pneumonia			
subjects affected / exposed	1 / 163 (0.61%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	1	3	0
Viral infection			
subjects affected / exposed	1 / 163 (0.61%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	1	3	0
Bronchopneumonia			
subjects affected / exposed	2 / 163 (1.23%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	2	1	0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 163 (0.61%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
Laryngitis			
subjects affected / exposed	0 / 163 (0.00%)	3 / 162 (1.85%)	0 / 163 (0.00%)
occurrences (all)	0	3	0
Pharyngitis			
subjects affected / exposed	2 / 163 (1.23%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	2	1	0
Sinusitis			
subjects affected / exposed	3 / 163 (1.84%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	3	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	2 / 163 (1.23%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis viral			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	1	1	0
Fungal skin infection			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	1	1	0
Impetigo			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	1	1	0
Otitis media acute			
subjects affected / exposed	2 / 163 (1.23%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	2	0	0

Pyoderma			
subjects affected / exposed	1 / 163 (0.61%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
Rhinitis			
subjects affected / exposed	0 / 163 (0.00%)	2 / 162 (1.23%)	1 / 163 (0.61%)
occurrences (all)	0	2	1
Candidiasis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis infective			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Herpangina			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Injection site abscess			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Pertussis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Pneumonia primary atypical			
subjects affected / exposed	0 / 163 (0.00%)	1 / 162 (0.62%)	0 / 163 (0.00%)
occurrences (all)	0	1	0

Respiratory tract infection viral subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Roseola subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 162 (0.62%) 1	0 / 163 (0.00%) 0
Skin bacterial infection subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Skin infection subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 162 (0.62%) 1	0 / 163 (0.00%) 0
Subcutaneous abscess subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 162 (0.62%) 1	0 / 163 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 162 (0.62%) 1	0 / 163 (0.00%) 0
Viral diarrhoea subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 162 (0.62%) 1	0 / 163 (0.00%) 0
Viral tonsillitis subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 162 (0.62%) 1	0 / 163 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Hand-foot-and-mouth disease subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Tonsillitis bacterial subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 162 (0.00%) 0	0 / 163 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite			

subjects affected / exposed	1 / 163 (0.61%)	2 / 162 (1.23%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
Abnormal weight gain			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	1	0	0
Weight gain poor			
subjects affected / exposed	1 / 163 (0.61%)	0 / 162 (0.00%)	1 / 163 (0.61%)
occurrences (all)	1	0	1
Dehydration			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 163 (0.00%)	0 / 162 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	After the Infant Series 7vPnC	13vPnC Toddler Dose	7vPnC Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 162 (4.32%)	108 / 155 (69.68%)	105 / 156 (67.31%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hyperaemia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	3 / 156 (1.92%)
occurrences (all)	0	2	3
Inflammation			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0

Injection site reaction			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Injection site exfoliation			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Injection site scar			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Vaccination site erythema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (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 SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 162 (0.00%)	36 / 116 (31.03%)	32 / 107 (29.91%)
occurrences (all)	0	36	32
Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 162 (0.00%)	2 / 110 (1.82%)	3 / 100 (3.00%)
occurrences (all)	0	2	3
Fever >40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Sysetmic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 162 (0.00%)	1 / 110 (0.91%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 162 (0.00%)	39 / 117 (33.33%)	46 / 118 (38.98%)
occurrences (all)	0	39	46
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 162 (0.00%)	84 / 125 (67.20%)	86 / 125 (68.80%)
occurrences (all)	0	84	86

Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 162 (0.00%)	36 / 117 (30.77%)	26 / 108 (24.07%)
occurrences (all)	0	36	26
Decreased sleep: Infant Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 162 (0.00%)	27 / 119 (22.69%)	22 / 107 (20.56%)
occurrences (all)	0	27	22
Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Fever >40°C : Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 3			
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Allergy to arthropod bite			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Food allergy			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	4 / 156 (2.56%)
occurrences (all)	0	2	4
Allergic cough			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Asthmatic crisis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Upper airway obstruction			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	2 / 162 (1.23%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	2 / 162 (1.23%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

Head injury			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Traumatic brain injury			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 162 (0.62%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	1	0	0
Hydrocele			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Ventricular septal defect			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypokinesia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Psychomotor skills impaired			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	1 / 156 (0.64%)
occurrences (all)	0	1	1
Lymphadenopathy			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Strabismus			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	3 / 156 (1.92%)
occurrences (all)	0	2	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	3 / 156 (1.92%)
occurrences (all)	0	0	3
Abdominal pain			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 162 (0.62%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	1	1	0
Inguinal hernia			

subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Oral mucosal discolouration			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	3 / 156 (1.92%)
occurrences (all)	0	2	3
Umbilical hernia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Pityriasis alba			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Tenderness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 162 (0.00%)	81 / 126 (64.29%)	67 / 126 (53.17%)
occurrences (all)	0	81	67
Tenderness (Significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 162 (0.00%)	21 / 115 (18.26%)	14 / 105 (13.33%)
occurrences (all)	0	21	14
Swelling (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 162 (0.00%)	13 / 113 (11.50%)	11 / 105 (10.48%)
occurrences (all)	0	13	11
Swelling (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 162 (0.00%)	9 / 111 (8.11%)	9 / 103 (8.74%)
occurrences (all)	0	9	9
Swelling (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 162 (0.00%)	6 / 113 (5.31%)	4 / 102 (3.92%)
occurrences (all)	0	6	4
Redness (Any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 162 (0.00%)	15 / 113 (13.27%)	9 / 103 (8.74%)
occurrences (all)	0	15	9
Redness (Mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 162 (0.00%)	14 / 113 (12.39%)	8 / 102 (7.84%)
occurrences (all)	0	14	8
Redness (Moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 162 (0.00%)	1 / 110 (0.91%)	1 / 101 (0.99%)
occurrences (all)	0	1	1
Tenderness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Swelling (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Redness (Any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Redness (Mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Recations 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Swelling (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Redness (Any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pyelocaliectasis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	2 / 156 (1.28%)
occurrences (all)	0	1	2
Arthralgia			

subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 162 (0.00%)	11 / 155 (7.10%)	7 / 156 (4.49%)
occurrences (all)	0	12	7
Nasopharyngitis			
subjects affected / exposed	0 / 162 (0.00%)	19 / 155 (12.26%)	16 / 156 (10.26%)
occurrences (all)	0	19	17
Gastroenteritis			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	1 / 156 (0.64%)
occurrences (all)	0	1	1
Perineal infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 162 (0.00%)	3 / 155 (1.94%)	1 / 156 (0.64%)
occurrences (all)	0	3	1
Varicella			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	2 / 156 (1.28%)
occurrences (all)	0	0	2
Exanthema subitum			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	2 / 156 (1.28%)
occurrences (all)	0	2	2
Otitis media			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	3 / 156 (1.92%)
occurrences (all)	0	2	3
Tracheobronchitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	2 / 156 (1.28%)
occurrences (all)	0	0	2
Viral rash			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	0 / 156 (0.00%)
occurrences (all)	0	2	0
Viral infection			
subjects affected / exposed	1 / 162 (0.62%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	1	0	1
Bronchopneumonia			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	1 / 156 (0.64%)
occurrences (all)	0	1	1
Conjunctivitis bacterial			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	0 / 156 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 162 (0.00%)	3 / 155 (1.94%)	1 / 156 (0.64%)
occurrences (all)	0	3	1
Sinusitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Conjunctivitis viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	6 / 156 (3.85%)
occurrences (all)	0	0	7
Pyoderma			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Injection site abscess			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Pneumonia primary atypical			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Roseola			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Skin bacterial infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 162 (0.00%)	6 / 155 (3.87%)	3 / 156 (1.92%)
occurrences (all)	0	6	3
Viral diarrhoea			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 162 (0.00%)	2 / 155 (1.29%)	0 / 156 (0.00%)
occurrences (all)	0	2	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Tonsillitis bacterial			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Abnormal weight gain			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	0 / 156 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 162 (0.00%)	1 / 155 (0.65%)	0 / 156 (0.00%)
occurrences (all)	0	1	0
Lactose intolerance			
subjects affected / exposed	0 / 162 (0.00%)	0 / 155 (0.00%)	1 / 156 (0.64%)
occurrences (all)	0	0	1

Notes:

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

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 August 2008	Revised the visit 5 and visit 7 windows (7- and 13-month visits) from the original 28 to 42 days to a range of 28 to 56 days for blood draws and AE collection.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported