Clinical trial results:
A Phase 4, Randomized, Open-label Trial Evaluating the Safety, Tolerability, and Immunogenicity of DTaP Vaccine in Healthy Infants Given with a 7-valent Pneumococcal Conjugate Vaccine in Japan.

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

Summary

EudraCT number	2014-004177-16
Trial protocol	Outside EU/EEA
Global end of trial date	24 March 2012

Results information

Result version number	v2 (current)
This version publication date	29 July 2016
First version publication date	02 August 2015
Version creation reason	• Correction of full data set Not completed reason having type "Other" with same other reason text

Trial information

Trial identification

Sponsor protocol code	B1841007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01250756
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: 6107A1-4000

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 May 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 March 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To demonstrate that the immune responses as measured by serum antibody responses to diphtheria toxin, tetanus toxin, pertussis toxin (PT) and filamentous haemagglutinin (FHA) induced by diphtheria, tetanus, and acellular pertussis vaccine (DTaP) given concomitantly with 7vPnC are comparable to the immune responses induced by DTaP given alone when measured 1 month after the 3-dose infant series.
2. To measure the immune response to 7vPnC 1 month after a 3-dose infant series as measured by serum immunoglobulin G (IgG) levels.
3. To evaluate the safety profile of 7vPnC given with DTaP 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 Council for Harmonisation (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	25 November 2010
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	Japan: 321
Worldwide total number of subjects	321
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)	321

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:

The study was conducted in Japan from 25 November 2010 to 24 March 2012.

Period 1

Period 1 title	Infant Series
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	7vPnC + DTaP - Infant Series

Arm description:

Subjects at 3 to 6 months of age received a single dose of 7-valent pneumococcal conjugate vaccine (7vPnC) subcutaneously followed by 2 single doses of 7vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of diphtheria, tetanus, and acellular pertussis vaccine (DTaP) subcutaneously administered concomitantly with each 7vPnC dose.

Arm type	Experimental
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	Prevenar
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects at 3 to 6 months of age received a single 0.5 mL dose of 7vPnC subcutaneously followed by 2 single 0.5 milliliter (mL) doses of 7vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series).

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

Dosage and administration details:

Subjects received a single 0.5 mL dose of DTaP subcutaneously followed by 2 single 0.5 mL doses of DTaP subcutaneously, 4 to 8 weeks after each previous dose (infant series)

Arm title	DTaP (Catch-up 7vPnC) - Infant Series

Arm description:

Subjects at 3 to 6 months of age received a single DTaP dose subcutaneously followed by 2 single DTaP doses subcutaneously, 4 to 8 weeks after each previous dose (infant series). Four to 6 weeks post-infant series, 2 single catch-up (CU) doses of 7vPnC (Prevenar) were administered subcutaneously at 4 to 6 weeks apart.

Arm type	Experimental
Investigational medicinal product name	DTaP
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects at 3 to 6 months of age received a single 0.5 mL dose of DTaP subcutaneously followed by 2 single 0.5 mL doses of DTaP subcutaneously, 4 to 8 weeks after each previous dose (infant series).

Number of subjects in period 1	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series
Started	161	160
Vaccinated Dose 1	159	158
Vaccinated Dose 2	147	157
Vaccinated Dose 3	133	155
Completed	133	153
Not completed	28	7
Consent withdrawn by subject	4	5
Unspecified	22	-
Randomized, Not Vaccinated	2	2

Period 2

Period 2 title	After Infant Series
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	7vPnC + DTaP - After the Infant Series

Arm description:

Subjects at 3 to 6 months of age received a single dose of 7vPnC subcutaneously followed by 2 single doses of 7vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 7vPnC dose.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	DTaP (Catch-up 7vPnC) - After the Infant Series

Arm description:

Subjects at 3 to 6 months of age received a single DTaP dose subcutaneously followed by 2 single DTaP doses subcutaneously, 4 to 8 weeks after each previous dose (infant series). Four to 6 weeks post-infant series, 2 single catch-up (CU) doses of 7vPnC (Prevenar) were administered subcutaneously, 4 to 6 weeks apart.

Arm type	Experimental

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

Dosage and administration details:

Subjects received 2 single catch-up doses of 7vPnC (Prevenar) administered subcutaneously, 4 to 6 weeks apart.

Number of subjects in period 2	7vPnC + DTaP - After the Infant Series	DTaP (Catch-up 7vPnC) - After the Infant Series
Started	133	153
Completed	122	149
Not completed	11	4
Consent withdrawn by subject	4	1
Adverse event, non-fatal	5	2
Unspecified	2	1

Period 3

Period 3 title	Toddler Dose
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	7vPnC + DTaP - Toddler Dose

Arm description:

Subjects received a single dose of 7vPnC subcutaneously at 12 to 15 months of age (toddler dose). A single dose of DTaP subcutaneously administered concomitantly with each 7vPnC dose.

Arm type	Experimental
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	Prevenar
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received a single 0.5 mL dose of 7vPnC subcutaneously at 12 to 15 months of age (toddler dose).

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

Dosage and administration details:

Subjects received a single 0.5 mL dose of DTaP subcutaneously at 12 to 15 months of age (toddler dose).

Arm title	DTaP (Catch-up 7vPnC) - Toddler Dose

Arm description:

Subjects received a single DTaP dose subcutaneously at 12 to 15 months of age (toddler dose) followed by a single CU dose of 7vPnC (Prevenar) subcutaneously 4 to 6 weeks post-toddler dose.

Arm type	Experimental
Investigational medicinal product name	DTaP
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received a single 0.5 mL DTaP dose subcutaneously at 12 to 15 months of age (toddler dose).

Number of subjects in period 3	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose
Started	122	149
Completed	122	148
Not completed	0	1
Adverse Event	-	1

Period 4

Period 4 title	After Toddler Dose
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	DTaP (Catch-up 7vPnC) - After the Toddler Dose

Arm description:

Subjects received a single DTaP dose subcutaneously at 12 to 15 months of age (toddler dose) followed by a single CU dose of 7vPnC (Prevenar) subcutaneously 4 to 6 weeks post-toddler dose.

Arm type	Experimental
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subject received a single 0.5 mL CU dose of 7vPnC (Prevenar) 4 to 6 weeks post-toddler dose.

Number of subjects in period 4[1]	DTaP (Catch-up 7vPnC) - After the Toddler Dose
Started	148
Completed	147
Not completed	1
Adverse event, non-fatal	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Since no subject continued in 7vPnC + DTaP arm after the toddler dose, so data for DTaP (Catch-up 7vPnC) arm has been reported.

Baseline characteristics

Reporting groups	
Reporting group title	7vPnC + DTaP - Infant Series
Reporting group description:	
Subjects at 3 to 6 months of age received a single dose of 7-valent pneumococcal conjugate vaccine (7vPnC) subcutaneously followed by 2 single doses of 7vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of diphtheria, tetanus, and acellular pertussis vaccine (DTaP) subcutaneously administered concomitantly with each 7vPnC dose.	
Reporting group title	DTaP (Catch-up 7vPnC) - Infant Series
Reporting group description:	
Subjects at 3 to 6 months of age received a single DTaP dose subcutaneously followed by 2 single DTaP doses subcutaneously, 4 to 8 weeks after each previous dose (infant series). Four to 6 weeks post-infant series, 2 single catch-up (CU) doses of 7vPnC (Prevenar) were administered subcutaneously at 4 to 6 weeks apart.	

Reporting group values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series	Total
Number of subjects	161	160	321
Age categorical Units: Subjects			
Age Continuous Units: months			
arithmetic mean	3.8	3.9	
standard deviation	± 0.91	± 0.94	-
Gender, Male/Female Units: participants			
Female	80	82	162
Male	81	78	159

End points

End points reporting groups

Reporting group title	7vPnC + DTaP - Infant Series

Reporting group description:

Subjects at 3 to 6 months of age received a single dose of 7-valent pneumococcal conjugate vaccine (7vPnC) subcutaneously followed by 2 single doses of 7vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of diphtheria, tetanus, and acellular pertussis vaccine (DTaP) subcutaneously administered concomitantly with each 7vPnC dose.

Reporting group title	DTaP (Catch-up 7vPnC) - Infant Series

Reporting group description:

Subjects at 3 to 6 months of age received a single DTaP dose subcutaneously followed by 2 single DTaP doses subcutaneously, 4 to 8 weeks after each previous dose (infant series). Four to 6 weeks post-infant series, 2 single catch-up (CU) doses of 7vPnC (Prevenar) were administered subcutaneously at 4 to 6 weeks apart.

Reporting group title	7vPnC + DTaP - After the Infant Series

Reporting group description:

Subjects at 3 to 6 months of age received a single dose of 7vPnC subcutaneously followed by 2 single doses of 7vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 7vPnC dose.

Reporting group title	DTaP (Catch-up 7vPnC) - After the Infant Series

Reporting group description:

Subjects at 3 to 6 months of age received a single DTaP dose subcutaneously followed by 2 single DTaP doses subcutaneously, 4 to 8 weeks after each previous dose (infant series). Four to 6 weeks post-infant series, 2 single catch-up (CU) doses of 7vPnC (Prevenar) were administered subcutaneously, 4 to 6 weeks apart.

Reporting group title	7vPnC + DTaP - Toddler Dose

Reporting group description:

Subjects received a single dose of 7vPnC subcutaneously at 12 to 15 months of age (toddler dose). A single dose of DTaP subcutaneously administered concomitantly with each 7vPnC dose.

Reporting group title	DTaP (Catch-up 7vPnC) - Toddler Dose

Reporting group description:

Subjects received a single DTaP dose subcutaneously at 12 to 15 months of age (toddler dose) followed by a single CU dose of 7vPnC (Prevenar) subcutaneously 4 to 6 weeks post-toddler dose.

Reporting group title	DTaP (Catch-up 7vPnC) - After the Toddler Dose

Reporting group description:

Subjects received a single DTaP dose subcutaneously at 12 to 15 months of age (toddler dose) followed by a single CU dose of 7vPnC (Prevenar) subcutaneously 4 to 6 weeks post-toddler dose.

Primary: Percentage of Subjects Achieving Predefined Antibody Levels for Diphtheria Toxoid, Tetanus Toxoid, and Pertussis Antigens 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Levels for Diphtheria Toxoid, Tetanus Toxoid, and Pertussis Antigens 1 Month After the Infant Series[1]

End point description:

Percentage of subjects achieving predefined antibody level along with the corresponding 95% confidence interval (CI) were presented. Exact 2-sided CI based on the observed proportion of subjects . Predefined antibody levels were 0.1 International Units/mL (IU/mL) for diphtheria, 0.01 IU/mL for tetanus, 5 Enzyme-linked Immunosorbent Assay (ELISA) units/mL (EU/mL) for pertussis toxoid (PT), and 5 EU/mL for filamentous hemagglutinin (FHA). Evaluable infant immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

Notes:

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

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	149		
Units: Percentage of subjects				
number (confidence interval 95%)				
Diphtheria	100 (97.2 to 100)	100 (97.6 to 100)		
Tetanus	100 (97.2 to 100)	100 (97.6 to 100)		
Pertussis toxoid (PT)	100 (97.2 to 100)	100 (97.6 to 100)		
Filamentous hemagglutinin (FHA)	100 (97.2 to 100)	100 (97.6 to 100)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) for Antigen-specific Diphtheria and Tetanus Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Diphtheria and Tetanus Antibody 1 Month After the Infant Series[2]

End point description:

Geometric mean concentrations (GMCs) were measured in IU/mL and corresponding 2-sided 95% confidence interval (CI) were evaluated for diphtheria and tetanus antibodies. Evaluable infant immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

Notes:

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

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	149		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diphtheria	1.38 (1.27 to 1.49)	0.99 (0.91 to 1.09)		
Tetanus	1.91 (1.69 to 2.16)	2.05 (1.83 to 2.29)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) for Antigen-specific Acellular Pertussis Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Acellular Pertussis Antibody 1 Month After the Infant Series[3]

End point description:

GMCs were measured in EU/mL and corresponding 2-sided 95% CI were evaluated for PT and FHA antibodies. Evaluable infant immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

Notes:

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

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	149		
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis toxoid (PT)	76.79 (70.81 to 83.28)	83.56 (77.54 to 90.05)		
Filamentous hemagglutinin (FHA)	72.89 (65.8 to 80.74)	77.85 (71.01 to 85.35)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=) 0.35 microgram per milliliter (mcg/mL) 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level Greater Than or Equal to (>=) 0.35 microgram per milliliter (mcg/mL) 1 Month After the Infant Series[4][5]

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% CI for the 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F and 23F) were presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable infant immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

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 endpoint.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for 7vPnC + DTaP - Infant Series reporting group only.

End point values	7vPnC + DTaP - Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	132			
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 4	100 (97.2 to 100)			
Serotype 6B	99.2 (95.9 to 100)			
Serotype 9V	100 (97.2 to 100)			
Serotype 14	99.2 (95.9 to 100)			
Serotype 18C	99.2 (95.8 to 100)			
Serotype 19F	97.7 (93.5 to 99.5)			
Serotype 23F	98.5 (94.6 to 99.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After

	the Infant Series[6][7]

End point description:

Antibody geometric mean concentrations (GMCs) for 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) were presented. GMC and corresponding 2-sided 95% CI were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Evaluable infant immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

Notes:

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

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for 7vPnC + DTaP - Infant Series reporting group only.

End point values	7vPnC + DTaP - Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	132			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	11.82 (10.5 to 13.31)			
Serotype 6B	4.23 (3.61 to 4.97)			
Serotype 9V	5.96 (5.37 to 6.62)			
Serotype 14	16.61 (14.66 to 18.81)			
Serotype 18C	5.48 (4.76 to 6.31)			
Serotype 19F	8.85 (7.54 to 10.4)			
Serotype 23F	4.17 (3.54 to 4.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Predefined Antibody Levels for Diphtheria Toxoid, Tetanus Toxoid, and Pertussis Antigens 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Predefined Antibody Levels for Diphtheria Toxoid, Tetanus Toxoid, and Pertussis Antigens 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving predefined antibody level along with the corresponding 95% CI were presented. Exact 2-sided CI based on the observed proportion of subjects. Predefined antibody levels were 0.1 IU/mL for diphtheria, 0.01 IU/mL for tetanus, 5 EU/mL for PT, and 5 EU/mL for FHA. Evaluable

toddler immunogenicity set: eligible subjects who received vaccine to which they were randomized at all 4 doses, had blood drawn within protocol-specified time, had at least 1 valid, determinate assay result after toddler dose for analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	146		
Units: Percentage of subjects				
number (confidence interval 95%)				
Diphtheria	100 (97 to 100)	100 (97.5 to 100)		
Tetanus	100 (97 to 100)	100 (97.5 to 100)		
Pertussis toxoid (PT)	100 (97 to 100)	100 (97.5 to 100)		
Filamentous hemagglutinin (FHA)	100 (97 to 100)	100 (97.5 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Diphtheria and Tetanus Antibody 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Diphtheria and Tetanus Antibody 1 Month After the Toddler Dose

End point description:

GMCs were measured in IU/mL and corresponding 2-sided 95% CI were evaluated for diphtheria and tetanus antibodies. Evaluable toddler immunogenicity set: eligible subjects who received vaccine to which they were randomized at all 4 doses, had blood drawn within protocol-specified time, had at least 1 valid, determinate assay result after toddler dose for analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	146		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diphtheria	2.56 (2.35 to 2.78)	2.14 (1.94 to 2.35)		
Tetanus	2.53 (2.26 to 2.82)	3.04 (2.74 to 3.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Antigen-specific Acellular Pertussis Antibody 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Antigen-specific Acellular Pertussis Antibody 1 Month After the Toddler Dose

End point description:

GMCs were measured in EU/mL and corresponding 2-sided 95% CI were evaluated for PT and FHA antibodies. Evaluable toddler immunogenicity set: eligible subjects who received vaccine to which they were randomized at all 4 doses, had blood drawn within protocol-specified time, had at least 1 valid, determinate assay result after toddler dose for analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	146		
Units: EU/mL				
geometric mean (confidence interval 95%)				
PT	106.54 (96.1 to 118.12)	130.62 (119.6 to 142.65)		
FHA	120.99 (109.75 to 133.39)	145.38 (132.41 to 159.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level >=0.35 mcg/mL 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level >=0.35 mcg/mL 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 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F and 23F) were presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable toddler immunogenicity set: eligible subjects who received vaccine to which they were randomized at all 4 doses, had blood drawn within protocol-specified time, had at least 1 valid, determinate assay result after toddler dose for analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	121			
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 4	100 (97 to 100)			
Serotype 6B	100 (97 to 100)			
Serotype 9V	100 (97 to 100)			
Serotype 14	100 (97 to 100)			
Serotype 18C	99.2 (95.5 to 100)			
Serotype 19F	99.2 (95.5 to 100)			
Serotype 23F	100 (97 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Toddler Dose

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

End point description:

Antibody GMCs for 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) were presented. GMC and corresponding 2-sided 95% CIs were evaluated. GMs were calculated using all subjects with available data for the specified blood draw. Evaluable toddler immunogenicity set: eligible subjects who received vaccine to which they were randomized at all 4 doses, had blood drawn within protocol-specified time, had at least 1 valid, determinate assay result after toddler dose for analysis,

received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	121			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	12.15 (10.35 to 14.26)			
Serotype 6B	10.66 (8.96 to 12.68)			
Serotype 9V	6.43 (5.57 to 7.42)			
Serotype 14	15.83 (13.81 to 18.14)			
Serotype 18C	6.53 (5.49 to 7.76)			
Serotype 19F	9.7 (8.15 to 11.56)			
Serotype 23F	10.17 (8.58 to 12.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) of Pneumococcal Antibodies From Pretoddler Dose to 1 Month After the Toddler Dose

End point title	Geometric Mean Fold Rise (GMFR) of Pneumococcal Antibodies From Pretoddler Dose to 1 Month After the Toddler Dose

End point description:

Geometric mean fold rises (GMFRs) for the 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) from prevaccination to 1 month postvaccination were computed using the logarithmically transformed assay results. CI for the GMFRs were back transformations of a CI based on the Student t distribution for the logarithmically transformed assay results. Evaluable toddler immunogenicity set: eligible subjects who received vaccine to which they were randomized at all 4 doses, had blood drawn within protocol-specified time, had at least 1 valid, determinate assay result after toddler dose for analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

Pre-toddler dose, 1 month after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	121			
Units: Fold Rise				
geometric mean (confidence interval 95%)				
Serotype 4	6.74 (5.75 to 7.9)			
Serotype 6B	5.89 (5.09 to 6.81)			
Serotype 9V	4.34 (3.81 to 4.93)			
Serotype 14	3.63 (3.22 to 4.09)			
Serotype 18C	6.9 (6.06 to 7.85)			
Serotype 19F	6.37 (5.35 to 7.59)			
Serotype 23F	8.1 (7.01 to 9.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level >=0.35 mcg/mL 1 Month After Catch-up Dose 3

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Level >=0.35 mcg/mL 1 Month After Catch-up Dose 3

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% CI for the 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F and 23F) were presented. Exact 2-sided CI based on the observed proportion of subjects. Catch-up immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 catch-up doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the catch-up dose 3

End point values	DTaP (Catch-up 7vPnC) - After the Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	148			
Units: Percentage of subjects				
number (confidence interval 95%)				

Serotype 4	100 (97.5 to 100)			
Serotype 6B	99.3 (96.3 to 100)			
Serotype 9V	100 (97.5 to 100)			
Serotype 14	100 (97.5 to 100)			
Serotype 18C	99.3 (96.3 to 100)			
Serotype 19F	100 (97.5 to 100)			
Serotype 23F	99.3 (96.3 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Catch-up Dose 3

End point title	Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After Catch-up Dose 3

End point description:

Antibody GMCs for 7 pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) were presented. GMC and corresponding 2-sided 95% CI were evaluated. GMs were calculated using all subjects with available data for the specified blood draw. Catch-up immunogenicity population: eligible subjects who received the vaccine to which they were randomized at all 3 catch-up doses, had blood drawn within the protocol-specified time frames, had at least 1 valid, determinate assay result for proposed analysis, received no prohibited vaccines, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the catch-up dose 3

End point values	DTaP (Catch-up 7vPnC) - After the Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	148			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	6.63 (5.91 to 7.44)			
Serotype 6B	4.3 (3.75 to 4.93)			
Serotype 9V	3.48 (3.12 to 3.89)			
Serotype 14	11.55 (10.3 to 12.95)			
Serotype 18C	3.1 (2.69 to 3.57)			

Serotype 19F	5.16 (4.45 to 5.99)			
Serotype 23F	4.41 (3.78 to 5.14)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions: Infant Series Dose 1 (3 to 6 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Infant Series Dose 1 (3 to 6 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was 7vPnC injection site in the 7vPnC+DTaP group, and DTaP injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'=subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 1 of the infant series

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152[8]	154[9]		
Units: Percentage of subjects				
number (not applicable)				
Erythema-Any (n= 152, 152)	57.2	14.5		
Erythema-Mild (n= 152, 151)	52.6	12.6		
Erythema-Moderate (n= 148, 152)	14.9	2		
Erythema-Severe (n= 148, 151)	0	0		
Induration-Any (n= 149, 153)	40.3	7.8		
Induration-Mild (n= 149, 153)	38.3	7.8		
Induration-Moderate (n= 148, 151)	10.1	0		
Induration-Severe (n= 148, 151)	0	0		
Tenderness-Any (n= 148, 151)	12.2	0.7		
Tenderness-Significant (n= 148, 151)	0	0		
Any local reaction (n= 152, 154)	66.4	15.6		

Notes:

[8] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

[9] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

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 to 8 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Infant Series Dose 2 (4 to 8 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was 7vPnC injection site in the 7vPnC+DTaP group, and DTaP injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 2 of the infant series

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143[10]	151[11]		
Units: Percentage of subjects				
number (not applicable)				
Erythema-Any (n= 142, 150)	64.1	39.3		
Erythema-Mild (n= 142, 150)	58.5	33.3		
Erythema-Moderate (n= 134, 147)	32.1	6.8		
Erythema-Severe (n= 133, 147)	0	0		
Induration-Any (n= 137, 150)	51.8	30		
Induration-Mild (n= 137, 150)	49.6	28.7		
Induration-Moderate (n= 134, 148)	23.9	6.8		
Induration-Severe (n= 133, 147)	0	0		
Tenderness-Any (n= 133, 147)	7.5	4.1		
Tenderness-Significant (n= 133, 147)	0	0		
Any local reaction (n= 143, 151)	69.2	45		

Notes:

[10] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

[11] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions: Infant Series Dose 3 (5 to 10 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Infant Series Dose 3 (5 to 10 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to

7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was 7vPnC injection site in the 7vPnC+DTaP group, and DTaP injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 3 of the infant series

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126[12]	145[13]		
Units: Percentage of subjects				
number (not applicable)				
Erythema-Any (n= 123, 144)	52.8	30.6		
Erythema-Mild (n= 123, 143)	46.3	28		
Erythema-Moderate (n= 120, 139)	20	5.8		
Erythema-Severe (n= 118, 138)	0	0		
Induration-Any (n= 124, 144)	44.4	19.4		
Induration-Mild (n= 124, 144)	42.7	19.4		
Induration-Moderate (n= 119, 139)	11.8	2.2		
Induration-Severe (n= 118, 138)	0	0		
Tenderness-Any (n= 119, 138)	5	3.6		
Tenderness-Significant (n= 118, 138)	0	0		
Any local reaction (n= 126, 145)	61.1	33.1		

Notes:

[12] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

[13] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions: Toddler Dose (12 to 15 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Toddler Dose (12 to 15 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was 7vPnC injection site in the 7vPnC+DTaP group, and DTaP injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110[14]	138[15]		
Units: Percentage of subject				
number (not applicable)				
Erythema-Any (n= 108, 137)	51.9	32.1		
Erythema-Mild (n= 106, 137)	48.1	28.5		
Erythema-Moderate (n= 102, 134)	23.5	7.5		
Erythema-Severe (n= 98, 133)	0	0		
Induration-Any (n= 108, 137)	42.6	23.4		
Induration-Mild (n= 108, 137)	40.7	19.7		
Induration-Moderate (n= 99, 133)	16.2	6.8		
Induration-Severe (n= 98, 133)	0	0		
Tenderness-Any (n= 99, 136)	11.1	4.4		
Tenderness-Significant (n= 98, 133)	0	0		
Any local reaction (n= 110, 138)	56.4	39.1		

Notes:

[14] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

[15] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions: Post Infant Series Catch-up Dose 1 (6 to 11.5 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Post Infant Series Catch-up Dose 1 (6 to 11.5 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was catch-up 7vPnC injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Catch-up Dose 1

End point values	DTaP (Catch-up 7vPnC) - After the Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	141[16]			
Units: Percentage of subjects				
number (not applicable)				
Erythema-Any (n= 139)	51.8			
Erythema-Mild (n= 139)	45.3			
Erythema-Moderate (n= 136)	10.3			
Erythema-Severe (n= 135)	0			
Induration-Any (n= 138)	34.8			
Induration-Mild (n= 138)	32.6			
Induration-Moderate (n= 135)	8.1			
Induration-Severe (n= 135)	0			
Tenderness-Any (n= 136)	8.1			
Tenderness-Significant (n= 135)	0			
Any local reaction (n= 141)	54.6			

Notes:

[16] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions: Post Infant Series Catch-up Dose 2 (7 to 13 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Post Infant Series Catch-up Dose 2 (7 to 13 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was catch-up 7vPnC injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Catch-up Dose 2

End point values	DTaP (Catch-up 7vPnC) - After the Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	145[17]			
Units: Percentage of subjects				
number (not applicable)				
Erythema-Any (n= 144)	50.7			

Erythema-Mild (n= 144)	45.1			
Erythema-Moderate (n= 140)	13.6			
Erythema-Severe (n= 138)	0			
Induration-Any (n= 144)	32.6			
Induration-Mild (n= 143)	30.1			
Induration-Moderate (n= 140)	15			
Induration-Severe (n= 138)	0			
Tenderness-Any (n= 139)	5			
Tenderness-Significant (n= 138)	0			
Any local reaction (n= 145)	55.2			

Notes:

[17] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions: Post Infant Series Catch-up Dose 3 (13 to 16.5 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions: Post Infant Series Catch-up Dose 3 (13 to 16.5 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Erythema and induration were scaled as Any (erythema and induration present); Mild (0.5 to 2.0 centimeters [cm]); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Injection site being evaluated for local reactions was catch-up 7vPnC injection site in the DTaP (Catch-up 7vPnC) group. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Catch-up Dose 3

End point values	DTaP (Catch-up 7vPnC) - After the Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	137[18]			
Units: Percentage of subjects				
number (not applicable)				
Erythema-Any (n= 134)	32.1			
Erythema-Mild (n= 133)	27.1			
Erythema-Moderate (n= 131)	9.9			
Erythema-Severe (n= 130)	0			
Induration-Any (n= 134)	27.6			
Induration-Mild (n= 133)	24.8			
Induration-Moderate (n= 131)	9.9			
Induration-Severe (n= 130)	0			
Tenderness-Any (n= 132)	6.8			

Tenderness-Significant (n= 130)	0			
Any local reaction (n= 137)	40.9			

Notes:

[18] - N= subjects reporting yes for at least 1 day or no for all days for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events: Infant Series Dose 1 (3 to 6 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Infant Series Dose 1 (3 to 6 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 1 of the infant series

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	154[19]	153[20]		
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=149,152)	18.8	15.8		
Fever >39 but =<40.0 degrees C(n=148,151)	2	2		
Fever >40 degrees C(n=148,151)	0	0		
Decreased appetite(n=148,151)	8.8	7.9		
Irritability(n=151,151)	15.2	9.3		
Increased sleep(n=150,153)	32	25.5		
Decreased sleep(n=151,151)	16.6	15.2		
Hives (urticaria)(n=148,151)	1.4	0.7		
Antipyretic medication to treat symptom(n=148,151)	1.4	1.3		
Any systemic event(n=154,153)	57.8	48.4		

Notes:

[19] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

[20] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

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 to 8 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Infant Series Dose 2 (4 to 8 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 2 of the infant series

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	142[21]	153[22]		
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=138,149)	25.4	15.4		
Fever >39 but =<40.0 degrees C(n=135,147)	2.2	0		
Fever >40 degrees C(n=133,147)	0	0.7		
Decreased appetite(n=135,147)	11.9	5.4		
Irritability(n=134,149)	19.4	12.1		
Increased sleep(n=136,148)	19.1	12.8		
Decreased sleep(n=140,151)	17.1	15.2		
Hives (urticaria)(n=133,147)	3	0		
Antipyretic medication to treat symptom(n=134,147)	2.2	2		
Any systemic event(n=142,153)	53.5	38.6		

Notes:

[21] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

[22] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events: Infant Series Dose 3 (5 to 10 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Infant Series Dose 3 (5 to 10 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 3 of the infant series

End point values	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122[23]	143[24]		
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=120,141)	19.2	14.9		
Fever >39 but =<40.0 degrees C(n=118,138)	1.7	0.7		
Fever >40 degrees C(n=118,138)	0	0		
Decreased appetite(n=119,138)	8.4	6.5		
Irritability(n=118,139)	10.2	7.2		
Increased sleep(n=119,141)	16	18.4		
Decreased sleep(n=120,140)	6.7	14.3		
Hives (urticaria)(n=119,138)	1.7	0		
Antipyretic medication to treat symptom(n=119,138)	1.7	2.2		
Any systemic event(n=122,143)	39.3	36.4		

Notes:

[23] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

[24] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events: Toddler Dose (12 to 15 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Toddler Dose (12 to 15 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after the toddler dose

End point values	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108[25]	138[26]		
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=103,135)	34	22.2		
Fever >39 but =<40.0 degrees C(n=99,132)	5.1	2.3		
Fever >40 degrees C(n=98,132)	1	0		
Decreased appetite(n=100,133)	9	8.3		
Irritability(n=100,134)	17	9.7		
Increased sleep(n=103,135)	20.4	15.6		
Decreased sleep(n=101,133)	10.9	7.5		
Hives (urticaria)(n=98,133)	1	0.8		
Antipyretic medication to treat symptom(n=98,133)	4.1	4.5		
Any systemic event(n=108,138)	52.8	39.9		

Notes:

[25] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

[26] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events: Post Infant Series Catch-up Dose 1 (6 to 11.5 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Post Infant Series Catch-up Dose 1 (6 to 11.5 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Catch-up Dose 1

End point values	DTaP (Catch-up 7vPnC) - After the Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	139[27]			
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=139)	32.4			

Fever >39 but =<40.0 degrees C(n=135)	2.2			
Fever >40 degrees C(n=135)	0			
Decreased appetite(n=136)	8.1			
Irritability(n=136)	12.5			
Increased sleep(n=136)	17.6			
Decreased sleep(n=136)	11.8			
Hives (urticaria)(n=135)	0.7			
Antipyretic medication to treat symptom(n=136)	5.9			
Any systemic event(n=139)	49.6			

Notes:

[27] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events: Post Infant Series Catch-up Dose 2 (7 to 13 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Post Infant Series Catch-up Dose 2 (7 to 13 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Catch-up Dose 2

End point values	DTaP (Catch-up 7vPnC) - After the Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	141[28]			
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=140)	32.1			
Fever >39 but =<40.0 degrees C(n=138)	5.1			
Fever >40 degrees C(n=138)	0.7			
Decreased appetite(n=138)	10.9			
Irritability(n=138)	11.6			
Increased sleep(n=138)	15.9			
Decreased sleep(n=139)	10.1			
Hives (urticaria)(n=138)	2.2			
Antipyretic medication to treat symptom(n=138)	5.1			

Any systemic event(n=141)	47.5			

Notes:

[28] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events: Post Infant Series Catch-up Dose 3 (13 to 16.5 Months of Age)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events: Post Infant Series Catch-up Dose 3 (13 to 16.5 Months of Age)

End point description:

Systemic events (any fever >= 37.5 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]), were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included all subjects who received at least 1 dose of study vaccine. 'n'= subjects reporting yes for at least 1 day or no for all days for the specified local reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Catch-up Dose 3

End point values	DTaP (Catch-up 7vPnC) - After the Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	136[29]			
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5 but =<39 degrees C(n=134)	26.9			
Fever >39 but =<40.0 degrees C(n=130)	0.8			
Fever >40 degrees C(n=130)	0			
Decreased appetite(n=130)	6.2			
Irritability(n=131)	9.2			
Increased sleep(n=131)	10.7			
Decreased sleep(n=131)	6.9			
Hives (urticaria)(n=131)	0.8			
Antipyretic medication to treat symptom(n=130)	1.5			
Any systemic event(n=136)	39			

Notes:

[29] - N= subjects reporting yes for at least 1 day or no for all days for any systemic event.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs: from signing ICF to visit 4(CU Dose 1: 28 to 42 days) for Group 1/visit 6(28 to 42 days)for Group 2 and from visit 7(Dose 4: 28 to 42 days)to visit 8(CU Dose 3: 28 to 42 days) for Group 1/to visit 9(28 to 42 days) for Group 2. SAEs: ICF to last visit

Adverse event reporting additional description:

Safety population: subjects who receive at least 1 dose of study vaccine. SAEs and AEs were grouped by system organ class and summarized. AEs included solicited AEs collected in electronic diary (local and systemic reactions; systematic assessment) and unsolicited events collected on case report form at each visit (nonsystematic assessment).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	7vPnC + DTaP - Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL doses of 7vPnC subcutaneously 4 to 8 weeks apart along with 3 single 0.5 mL doses of DTaP subcutaneously (infant series), assessed from Infant Dose 1 through the blood draw 28 to 42 days post-infant series.

Reporting group title	DTaP (Catch-up 7vPnC)- Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL DTaP doses subcutaneously 4 to 8 weeks apart (infant series) followed by 2 single catch-up (CU) doses, CU Dose 1 and CU Dose 2 (separated by 4 to 6 weeks), of 7vPnC (Prevenar) 4 to 6 weeks post-infant series, assessed from Infant Dose 1 through the CU Dose 1.

Reporting group title	7vPnC + DTaP - After the Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL doses of 7vPnC subcutaneously 4 to 8 weeks apart along with 3 single 0.5 mL doses of DTaP subcutaneously (infant series), assessed after the infant series blood draw to the toddler dose.

Reporting group title	DTaP (Catch-up 7vPnC) - After the Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL DTaP doses subcutaneously 4 to 8 weeks apart (infant series) followed by 2 single catch-up (CU) doses, CU Dose 1 and CU Dose 2 (separated by 4 to 6 weeks), of 7vPnC (Prevenar) 4 to 6 weeks post-infant series, assessed after CU Dose 1 to the toddler dose.

Reporting group title	7vPnC + DTaP - Toddler Dose

Reporting group description:

Subjects who received a single 0.5 mL dose of 7vPnC subcutaneously (toddler dose) along with 0.5 mL dose of DTaP subcutaneously, assessed from the toddler dose through the blood draw 28 to 42 days post-toddler dose.

Reporting group title	DTaP (Catch-up 7vPnC) - Toddler Dose

Reporting group description:

Subjects who received a single 0.5 mL DTaP dose subcutaneously (toddler dose) followed by a single catch-up (CU) dose (CU Dose 3) of 7vPnC (Prevenar) 4 to 6 weeks after toddler dose; assessed from toddler dose through the CU Dose 3.

Reporting group title	DTaP (Catch-up 7vPnC) - After the Toddler Dose

Reporting group description:

Subjects who received a single 0.5 mL DTaP dose subcutaneously (toddler dose) followed by a single catch-up (CU) dose (CU Dose 3) of 7vPnC (Prevenar) 4 to 6 weeks after toddler dose; assessed after the CU Dose 3 to 28 to 42 days post-CU Dose 3.

Serious adverse events	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC)- Infant Series	7vPnC + DTaP - After the Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 159 (1.89%)	7 / 158 (4.43%)	10 / 159 (6.29%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (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
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	4 / 159 (2.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (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
Gastrointestinal disorders			
Inguinal hernia			

subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (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
Intussusception			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (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
Apnoea			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (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
Tonsillar hypertrophy			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (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
Infantile asthma			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
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			
Gastroenteritis viral			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory syncytial virus bronchitis			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (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
Bronchitis bacterial			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (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
Bronchitis			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			

subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (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	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (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			
Weight gain poor			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	DTaP (Catch-up 7vPnC) - After the Infant Series	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 158 (4.43%)	0 / 122 (0.00%)	4 / 149 (2.68%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Burns second degree			

subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (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
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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			
Febrile convulsion			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (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			

Adenoidal hypertrophy			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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
Apnoea			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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
Tonsillar hypertrophy			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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
Infantile asthma			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 failure			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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			
Gastroenteritis viral			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 syncytial virus bronchitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 syncytial virus			

bronchiolitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 respiratory syncytial viral			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (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 mycoplasmal			

subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (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 / 158 (0.00%)	0 / 122 (0.00%)	2 / 149 (1.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Weight gain poor			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	DTaP (Catch-up 7vPnC) - After the Toddler Dose		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 149 (0.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Kawasaki's disease			

subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apnoea			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillar hypertrophy			

subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile asthma				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Gastroenteritis viral				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis bacterial				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenovirus infection				

subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exanthema subitum				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis adenovirus				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia mycoplasmal				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				

subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Weight gain poor			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC)- Infant Series	7vPnC + DTaP - After the Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	123 / 159 (77.36%)	126 / 158 (79.75%)	20 / 159 (12.58%)
General disorders and administration site conditions			
Vaccination site erythema			
subjects affected / exposed	5 / 159 (3.14%)	10 / 158 (6.33%)	0 / 159 (0.00%)
occurrences (all)	9	13	0
Pyrexia			
subjects affected / exposed	5 / 159 (3.14%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	5	0	0
Vaccination site induration			
subjects affected / exposed	1 / 159 (0.63%)	4 / 158 (2.53%)	0 / 159 (0.00%)
occurrences (all)	1	4	0
Injection site induration			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	1	2	0
Vaccination site swelling			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
Application site erythema			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	2	0
Injection site haemorrhage			

subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Fever≥37.5°C but≤39°C:Infant Series Dose 1/After Infant Series Dose1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	28 / 149 (18.79%)	24 / 152 (15.79%)	0 / 159 (0.00%)
occurrences (all)	28	24	0
Fever ≥37.5°C but ≤39°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	35 / 138 (25.36%)	23 / 149 (15.44%)	0 / 159 (0.00%)
occurrences (all)	35	23	0
Fever ≥37.5°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	23 / 120 (19.17%)	21 / 141 (14.89%)	0 / 159 (0.00%)
occurrences (all)	23	21	0
Fever>39°C but ≤40°C: Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddle Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	3 / 148 (2.03%)	3 / 151 (1.99%)	0 / 159 (0.00%)
occurrences (all)	3	3	0
Fever>39°C but ≤40°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	3 / 135 (2.22%)	0 / 147 (0.00%)	0 / 159 (0.00%)
occurrences (all)	3	0	0
Fever>39°C but ≤40°C: Infant	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one		

Series Dose 3	occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	2 / 118 (1.69%)	1 / 138 (0.72%)	0 / 159 (0.00%)
occurrences (all)	2	1	0
Fever >40.0°C: Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose / After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 148 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	151	0
Fever >40.0°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 133 (0.00%)	1 / 147 (0.68%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Decreased appetite- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	13 / 148 (8.78%)	12 / 151 (7.95%)	0 / 159 (0.00%)
occurrences (all)	13	12	0
Decreased appetite- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	16 / 135 (11.85%)	8 / 147 (5.44%)	0 / 159 (0.00%)
occurrences (all)	16	8	0
Decreased appetite- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[11]	10 / 119 (8.40%)	9 / 138 (6.52%)	0 / 159 (0.00%)
occurrences (all)	10	9	0
Irritability- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose / After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[12]	23 / 151 (15.23%)	14 / 151 (9.27%)	0 / 159 (0.00%)
occurrences (all)	23	14	0
Irritability- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[13]	26 / 134 (19.40%)	18 / 149 (12.08%)	0 / 159 (0.00%)
occurrences (all)	26	18	0
Irritability- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[14]	12 / 118 (10.17%)	10 / 139 (7.19%)	0 / 159 (0.00%)
occurrences (all)	12	10	0
Increased sleep- Infant Series Dose 1 / After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[15]	48 / 150 (32.00%)	39 / 153 (25.49%)	0 / 159 (0.00%)
occurrences (all)	48	39	0
Increased sleep- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[16]	26 / 136 (19.12%)	19 / 148 (12.84%)	0 / 159 (0.00%)
occurrences (all)	26	19	0
Increased sleep- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[17] occurrences (all)	19 / 119 (15.97%) 19	26 / 141 (18.44%) 26	0 / 159 (0.00%) 0
Decreased sleep- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[18] occurrences (all)	25 / 151 (16.56%) 25	23 / 151 (15.23%) 23	0 / 159 (0.00%) 0
Decreased sleep- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	24 / 140 (17.14%) 24	23 / 151 (15.23%) 23	0 / 159 (0.00%) 0
Decreased sleep- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	8 / 120 (6.67%) 8	20 / 140 (14.29%) 20	0 / 159 (0.00%) 0
Hives (urticaria)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[21] occurrences (all)	4 / 133 (3.01%) 4	0 / 147 (0.00%) 0	0 / 159 (0.00%) 0
Hives (urticaria)- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[22]	2 / 148 (1.35%)	1 / 151 (0.66%)	0 / 159 (0.00%)
occurrences (all)	2	1	0
Hives (urticaria)- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	2 / 119 (1.68%)	0 / 138 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	2 / 159 (1.26%)	1 / 158 (0.63%)	6 / 159 (3.77%)
occurrences (all)	4	1	6
Allergy to arthropod bite			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Milk allergy			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	1 / 159 (0.63%)
occurrences (all)	0	1	1
Allergy to animal			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Anaphylactic reaction			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	1 / 159 (0.63%)
occurrences (all)	2	1	1
Rhinorrhoea			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	1	1	0

Asthma			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Infantile asthma			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Rhinitis perennial			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Excoriation			
subjects affected / exposed	0 / 159 (0.00%)	2 / 158 (1.27%)	0 / 159 (0.00%)
occurrences (all)	0	2	0
Contusion			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Thermal burn			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0

Wound			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	2 / 159 (1.26%)
occurrences (all)	2	3	2
Eye disorders			
Conjunctivitis			
subjects affected / exposed	6 / 159 (3.77%)	14 / 158 (8.86%)	0 / 159 (0.00%)
occurrences (all)	6	14	0
Eye discharge			
subjects affected / exposed	3 / 159 (1.89%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	3	3	0
Keratitis			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Eyelid oedema			

subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	8 / 159 (5.03%)	8 / 158 (5.06%)	0 / 159 (0.00%)
occurrences (all)	9	8	0
Diarrhoea			
subjects affected / exposed	7 / 159 (4.40%)	9 / 158 (5.70%)	1 / 159 (0.63%)
occurrences (all)	9	12	1
Haematochezia			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Ileus			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Intussusception			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	26 / 159 (16.35%)	22 / 158 (13.92%)	2 / 159 (1.26%)
occurrences (all)	35	32	3
Eczema infantile			
subjects affected / exposed	6 / 159 (3.77%)	8 / 158 (5.06%)	1 / 159 (0.63%)
occurrences (all)	9	13	1
Dermatitis diaper			
subjects affected / exposed	16 / 159 (10.06%)	13 / 158 (8.23%)	1 / 159 (0.63%)
occurrences (all)	23	19	2
Asteatosis			
subjects affected / exposed	5 / 159 (3.14%)	4 / 158 (2.53%)	0 / 159 (0.00%)
occurrences (all)	9	7	0
Dry skin			
subjects affected / exposed	1 / 159 (0.63%)	6 / 158 (3.80%)	1 / 159 (0.63%)
occurrences (all)	2	14	2
Heat rash			
subjects affected / exposed	3 / 159 (1.89%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	3	4	0
Dermatitis atopic			
subjects affected / exposed	4 / 159 (2.52%)	0 / 158 (0.00%)	3 / 159 (1.89%)
occurrences (all)	8	0	3
Dermatitis			
subjects affected / exposed	1 / 159 (0.63%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	2	4	0
Dermatitis contact			
subjects affected / exposed	3 / 159 (1.89%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	3	0	0
Erythema			
subjects affected / exposed	2 / 159 (1.26%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	2	1	0
Rash generalised			
subjects affected / exposed	0 / 159 (0.00%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	0	4	0
Urticaria			

subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	1 / 159 (0.63%)
occurrences (all)	1	1	1
Petechiae			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Generalised erythema			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Erythema (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Dictionary version was not captured, hence 0.0 is mentioned.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[24]	87 / 152 (57.24%)	22 / 152 (14.47%)	0 / 158 (0.00%)
occurrences (all)	87	22	0
Erythema (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[25]	91 / 142 (64.08%)	59 / 150 (39.33%)	0 / 159 (0.00%)
occurrences (all)	91	59	0
Erythema (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[26]	65 / 123 (52.85%)	44 / 144 (30.56%)	0 / 159 (0.00%)
occurrences (all)	65	44	0
Erythema (Mild)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[27]	83 / 142 (58.45%)	50 / 150 (33.33%)	0 / 159 (0.00%)
occurrences (all)	93	50	0
Erythema (Mild)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[28]	80 / 152 (52.63%)	19 / 151 (12.58%)	0 / 159 (0.00%)
occurrences (all)	80	19	0
Erythema (Mild)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[29]	57 / 123 (46.34%)	40 / 143 (27.97%)	0 / 159 (0.00%)
occurrences (all)	57	40	0
Erythema (Moderate)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[30]	22 / 148 (14.86%)	3 / 152 (1.97%)	0 / 159 (0.00%)
occurrences (all)	22	3	0
Erythema (Moderate)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[31]	43 / 134 (32.09%)	10 / 147 (6.80%)	0 / 159 (0.00%)
occurrences (all)	43	10	0
Erythema (Moderate)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[32]	24 / 120 (20.00%)	8 / 139 (5.76%)	0 / 159 (0.00%)
occurrences (all)	24	8	0
Induration (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[33]	60 / 149 (40.27%)	12 / 153 (7.84%)	0 / 159 (0.00%)
occurrences (all)	60	12	0
Induration (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[34]	71 / 137 (51.82%)	45 / 150 (30.00%)	0 / 159 (0.00%)
occurrences (all)	71	45	0
Induration (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[35]	55 / 124 (44.35%)	28 / 144 (19.44%)	0 / 159 (0.00%)
occurrences (all)	55	28	0
Induration (Mild)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[36]	57 / 149 (38.26%)	12 / 153 (7.84%)	0 / 159 (0.00%)
occurrences (all)	57	12	0
Induration (Mild)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[37]	68 / 137 (49.64%)	43 / 150 (28.67%)	0 / 159 (0.00%)
occurrences (all)	68	43	0
Induration (Mild)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[38]	53 / 124 (42.74%)	28 / 144 (19.44%)	0 / 159 (0.00%)
occurrences (all)	53	28	0
Induration (Moderate)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[39]	15 / 148 (10.14%)	0 / 151 (0.00%)	0 / 158 (0.00%)
occurrences (all)	15	0	0
Induration (Moderate)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[40]	32 / 134 (23.88%)	10 / 148 (6.76%)	0 / 158 (0.00%)
occurrences (all)	32	10	0
Induration (Moderate)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[41]	14 / 119 (11.76%)	3 / 139 (2.16%)	0 / 159 (0.00%)
occurrences (all)	14	3	0
Tenderness (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[42]	18 / 148 (12.16%)	1 / 151 (0.66%)	0 / 159 (0.00%)
occurrences (all)	18	1	0
Tenderness (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[43]	10 / 133 (7.52%)	6 / 147 (4.08%)	0 / 159 (0.00%)
occurrences (all)	10	6	0
Tenderness (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[44]	6 / 119 (5.04%)	5 / 138 (3.62%)	0 / 159 (0.00%)
occurrences (all)	6	5	0
Infections and infestations			
Nasopharyngitis subjects affected / exposed	49 / 159 (30.82%)	59 / 158 (37.34%)	1 / 159 (0.63%)
occurrences (all)	84	107	1
Upper respiratory tract infection subjects affected / exposed	35 / 159 (22.01%)	22 / 158 (13.92%)	5 / 159 (3.14%)
occurrences (all)	55	31	5
Gastroenteritis subjects affected / exposed	19 / 159 (11.95%)	12 / 158 (7.59%)	0 / 159 (0.00%)
occurrences (all)	24	12	0
Bronchitis subjects affected / exposed	10 / 159 (6.29%)	11 / 158 (6.96%)	0 / 159 (0.00%)
occurrences (all)	11	11	0
Influenza subjects affected / exposed	16 / 159 (10.06%)	12 / 158 (7.59%)	0 / 159 (0.00%)
occurrences (all)	16	12	0
Exanthema subitum subjects affected / exposed	6 / 159 (3.77%)	13 / 158 (8.23%)	0 / 159 (0.00%)
occurrences (all)	7	13	0

Gastroenteritis viral			
subjects affected / exposed	7 / 159 (4.40%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	8	3	0
Varicella			
subjects affected / exposed	5 / 159 (3.14%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	5	3	0
Otitis media			
subjects affected / exposed	5 / 159 (3.14%)	2 / 158 (1.27%)	0 / 159 (0.00%)
occurrences (all)	5	2	0
Impetigo			
subjects affected / exposed	2 / 159 (1.26%)	5 / 158 (3.16%)	0 / 159 (0.00%)
occurrences (all)	3	5	0
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 159 (1.26%)	5 / 158 (3.16%)	0 / 159 (0.00%)
occurrences (all)	2	5	0
Bronchiolitis			
subjects affected / exposed	5 / 159 (3.14%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	5	1	0
Otitis media acute			
subjects affected / exposed	0 / 159 (0.00%)	5 / 158 (3.16%)	0 / 159 (0.00%)
occurrences (all)	0	6	0
Pharyngitis			
subjects affected / exposed	1 / 159 (0.63%)	5 / 158 (3.16%)	0 / 159 (0.00%)
occurrences (all)	2	6	0
Enteritis infectious			
subjects affected / exposed	0 / 159 (0.00%)	3 / 158 (1.90%)	0 / 159 (0.00%)
occurrences (all)	0	5	0
Rhinitis			
subjects affected / exposed	1 / 159 (0.63%)	2 / 158 (1.27%)	0 / 159 (0.00%)
occurrences (all)	1	2	0
Gastroenteritis rotavirus			
subjects affected / exposed	2 / 159 (1.26%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 159 (0.00%)	2 / 158 (1.27%)	0 / 159 (0.00%)
occurrences (all)	0	4	0

Oral candidiasis			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	2	1	0
Otitis externa			
subjects affected / exposed	2 / 159 (1.26%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Paronychia			
subjects affected / exposed	2 / 159 (1.26%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	1 / 159 (0.63%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	1	2	0
Adenovirus infection			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis viral			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Croup infectious			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Genital candidiasis			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0

Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	2	0	0
Mucocutaneous candidiasis			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	2	0
Hordeolum			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Rotavirus infection			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Staphylococcal scalded skin syndrome			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Vaccination site infection			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	1 / 159 (0.63%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis bacterial			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Candidiasis			

subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Otitis media bacterial			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Candida nappy rash			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 159 (0.00%)	0 / 158 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 159 (0.00%)	1 / 158 (0.63%)	0 / 159 (0.00%)
occurrences (all)	0	3	0

Non-serious adverse events	DTaP (Catch-up 7vPnC) - After the Infant Series	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	129 / 158 (81.65%)	72 / 122 (59.02%)	96 / 149 (64.43%)
General disorders and administration site conditions			
Vaccination site erythema			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	4 / 158 (2.53%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
Vaccination site induration			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Injection site induration			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Application site erythema			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Fever≥37.5°C but≤39°C:Infant Series Dose 1/After Infant Series Dose1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	45 / 139 (32.37%)	35 / 103 (33.98%)	30 / 135 (22.22%)
occurrences (all)	45	35	30
Fever ≥37.5°C but ≤39°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[2]	45 / 140 (32.14%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	45	0	0
Fever ≥37.5°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Fever>39°C but ≤40°C: Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddle Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	3 / 135 (2.22%)	5 / 99 (5.05%)	3 / 132 (2.27%)
occurrences (all)	3	5	3
Fever>39°C but ≤40°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	7 / 138 (5.07%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	7	0	0
Fever>39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Fever >40.0°C: Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose / After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 135 (0.00%)	1 / 98 (1.02%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Fever >40.0°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here		

	0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	1 / 138 (0.72%) 1	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Decreased appetite- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	11 / 136 (8.09%) 11	9 / 100 (9.00%) 9	11 / 133 (8.27%) 11
Decreased appetite- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	15 / 138 (10.87%) 15	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Decreased appetite- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	0 / 158 (0.00%) 0	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Irritability- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose / After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	17 / 136 (12.50%) 17	17 / 100 (17.00%) 17	13 / 134 (9.70%) 13
Irritability- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[13]	16 / 138 (11.59%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	16	0	0
Irritability- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Increased sleep- Infant Series Dose 1 / After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[15]	24 / 136 (17.65%)	21 / 103 (20.39%)	21 / 135 (15.56%)
occurrences (all)	24	21	21
Increased sleep- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[16]	22 / 138 (15.94%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	22	0	0
Increased sleep- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Decreased sleep- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[18]	16 / 136 (11.76%)	11 / 101 (10.89%)	10 / 133 (7.52%)
occurrences (all)	16	11	10
Decreased sleep- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	14 / 139 (10.07%) 14	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Decreased sleep- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	0 / 158 (0.00%) 0	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Hives (urticaria)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[21] occurrences (all)	3 / 138 (2.17%) 3	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Hives (urticaria)- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[22] occurrences (all)	1 / 135 (0.74%) 1	1 / 98 (1.02%) 1	1 / 133 (0.75%) 1
Hives (urticaria)- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	0 / 158 (0.00%) 0	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Immune system disorders			
Food allergy subjects affected / exposed occurrences (all)	6 / 158 (3.80%) 9	1 / 122 (0.82%) 1	0 / 149 (0.00%) 0
Allergy to arthropod bite			

subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Allergy to animal			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	1	1	0
Anaphylactic reaction			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 158 (0.00%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	3 / 158 (1.90%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	4	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Infantile asthma			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Rhinitis perennial			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Excoriation			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	1	1	0
Contusion			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	3 / 149 (2.01%)
occurrences (all)	0	0	3
Joint dislocation			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 158 (0.00%)	1 / 122 (0.82%)	1 / 149 (0.67%)
occurrences (all)	0	1	1
Arthropod bite			
subjects affected / exposed	4 / 158 (2.53%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	6	1	0
Wound			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Arthropod sting			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Face injury			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 158 (0.00%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	0	1	0
Lip injury			

subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	4	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	9 / 158 (5.70%)	1 / 122 (0.82%)	4 / 149 (2.68%)
occurrences (all)	12	1	5
Eye discharge			
subjects affected / exposed	2 / 158 (1.27%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	2	1	0
Keratitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	6 / 158 (3.80%)	1 / 122 (0.82%)	1 / 149 (0.67%)
occurrences (all)	10	1	1
Diarrhoea			
subjects affected / exposed	8 / 158 (5.06%)	6 / 122 (4.92%)	6 / 149 (4.03%)
occurrences (all)	8	6	7
Haematochezia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			

subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Intussusception			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 158 (1.27%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	2	1	0
Stomatitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	4 / 158 (2.53%)	2 / 122 (1.64%)	3 / 149 (2.01%)
occurrences (all)	5	2	3
Eczema infantile			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Dermatitis diaper			
subjects affected / exposed	13 / 158 (8.23%)	7 / 122 (5.74%)	2 / 149 (1.34%)
occurrences (all)	14	7	2
Asteatosis			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	1 / 149 (0.67%)
occurrences (all)	1	1	1

Dry skin			
subjects affected / exposed	2 / 158 (1.27%)	1 / 122 (0.82%)	1 / 149 (0.67%)
occurrences (all)	2	1	1
Heat rash			
subjects affected / exposed	16 / 158 (10.13%)	2 / 122 (1.64%)	1 / 149 (0.67%)
occurrences (all)	24	2	1
Dermatitis atopic			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	3	0	0
Dermatitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 158 (0.00%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Rash generalised			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	3 / 158 (1.90%)	0 / 122 (0.00%)	2 / 149 (1.34%)
occurrences (all)	3	0	2
Petechiae			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	1 / 158 (0.63%)	2 / 122 (1.64%)	1 / 149 (0.67%)
occurrences (all)	1	2	1
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0

Generalised erythema			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Eczema asteatotic			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Erythema (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Dictionary version was not captured, hence 0.0 is mentioned.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	72 / 139 (51.80%)	56 / 108 (51.85%)	44 / 137 (32.12%)
occurrences (all)	72	56	44
Erythema (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	73 / 144 (50.69%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	73	0	0
Erythema (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	65 / 144 (45.14%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	65	0	0
Erythema (Mild)- Infant Series Dose 1 / After Infant Series Dose 1 /	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one		

Toddler Dose	occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	63 / 139 (45.32%)	51 / 106 (48.11%)	39 / 137 (28.47%)
occurrences (all)	63	51	39
Erythema (Mild)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	14 / 136 (10.29%)	24 / 102 (23.53%)	10 / 134 (7.46%)
occurrences (all)	14	24	10
Erythema (Moderate)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	19 / 140 (13.57%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	19	0	0
Erythema (Moderate)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Induration (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[33]	48 / 138 (34.78%)	46 / 108 (42.59%)	32 / 137 (23.36%)
occurrences (all)	48	46	32
Induration (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[34]	47 / 144 (32.64%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	47	0	0
Induration (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Induration (Mild)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[36]	45 / 138 (32.61%)	44 / 108 (40.74%)	27 / 137 (19.71%)
occurrences (all)	45	44	27
Induration (Mild)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[37]	43 / 143 (30.07%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	43	0	0
Induration (Mild)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	11 / 135 (8.15%) 11	16 / 99 (16.16%) 16	9 / 133 (6.77%) 9
Induration (Moderate)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[40] occurrences (all)	21 / 140 (15.00%) 21	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Induration (Moderate)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[41] occurrences (all)	0 / 158 (0.00%) 0	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Tenderness (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	11 / 136 (8.09%) 11	11 / 99 (11.11%) 11	6 / 136 (4.41%) 6
Tenderness (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[43] occurrences (all)	7 / 139 (5.04%) 7	0 / 122 (0.00%) 0	0 / 149 (0.00%) 0
Tenderness (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[44]	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	63 / 158 (39.87%)	27 / 122 (22.13%)	43 / 149 (28.86%)
occurrences (all)	96	30	45
Upper respiratory tract infection			
subjects affected / exposed	27 / 158 (17.09%)	17 / 122 (13.93%)	19 / 149 (12.75%)
occurrences (all)	38	18	21
Gastroenteritis			
subjects affected / exposed	13 / 158 (8.23%)	2 / 122 (1.64%)	4 / 149 (2.68%)
occurrences (all)	14	2	4
Bronchitis			
subjects affected / exposed	17 / 158 (10.76%)	11 / 122 (9.02%)	12 / 149 (8.05%)
occurrences (all)	25	11	13
Influenza			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Exanthema subitum			
subjects affected / exposed	21 / 158 (13.29%)	2 / 122 (1.64%)	7 / 149 (4.70%)
occurrences (all)	23	2	7
Gastroenteritis viral			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Varicella			
subjects affected / exposed	2 / 158 (1.27%)	2 / 122 (1.64%)	3 / 149 (2.01%)
occurrences (all)	2	2	3
Otitis media			
subjects affected / exposed	9 / 158 (5.70%)	4 / 122 (3.28%)	2 / 149 (1.34%)
occurrences (all)	11	4	2
Impetigo			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	3	0	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 158 (0.00%)	2 / 122 (1.64%)	0 / 149 (0.00%)
occurrences (all)	0	2	0

Bronchiolitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	4 / 158 (2.53%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	6	0	0
Pharyngitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	1	1	0
Rhinitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	3 / 149 (2.01%)
occurrences (all)	0	0	3
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Oral candidiasis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	1 / 149 (0.67%)
occurrences (all)	1	1	1

Adenovirus infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis viral			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Genital candidiasis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	11 / 158 (6.96%)	4 / 122 (3.28%)	6 / 149 (4.03%)
occurrences (all)	13	4	6
Mucocutaneous candidiasis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1

Sinusitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Staphylococcal scalded skin syndrome			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Vaccination site infection			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	1 / 149 (0.67%)
occurrences (all)	1	1	1
Gastroenteritis bacterial			
subjects affected / exposed	2 / 158 (1.27%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	2	0	0
Candidiasis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	1	0	1
Herpangina			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	2	1	0
Herpes simplex			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Localised infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Otitis media bacterial			

subjects affected / exposed	1 / 158 (0.63%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	1	0	0
Candida nappy rash			
subjects affected / exposed	0 / 158 (0.00%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	0	1	0
Bronchopneumonia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	1 / 149 (0.67%)
occurrences (all)	0	0	1
Acute sinusitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 158 (0.00%)	0 / 122 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	1 / 158 (0.63%)	1 / 122 (0.82%)	0 / 149 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	DTaP (Catch-up 7vPnC) - After the Toddler Dose		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	85 / 149 (57.05%)		
General disorders and administration site conditions			
Vaccination site erythema			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Vaccination site induration			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Injection site induration			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Vaccination site swelling			

subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Application site erythema			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Injection site haemorrhage			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Fever≥37.5°C but≤39°C:Infant Series Dose 1/After Infant Series Dose1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	36 / 134 (26.87%)		
occurrences (all)	36		
Fever ≥37.5°C but ≤39°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 149 (0.00%)		
occurrences (all)	0		
Fever ≥37.5°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 149 (0.00%)		
occurrences (all)	0		
Fever>39°C but ≤40°C: Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddle Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	1 / 130 (0.77%)		
occurrences (all)	1		
Fever>39°C but ≤40°C: Infant Series Dose 2 / After Infant Series	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here		

Dose 2	0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 149 (0.00%)		
occurrences (all)	0		
Fever>39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 149 (0.00%)		
occurrences (all)	0		
Fever >40.0°C: Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose / After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 130 (0.00%)		
occurrences (all)	0		
Fever >40.0°C: Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 149 (0.00%)		
occurrences (all)	0		
Decreased appetite- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	8 / 130 (6.15%)		
occurrences (all)	8		
Decreased appetite- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[10]	0 / 149 (0.00%)		
occurrences (all)	0		
Decreased appetite- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 149 (0.00%)		
occurrences (all)	0		
Irritability- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose / After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	12 / 131 (9.16%)		
occurrences (all)	12		
Irritability- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 149 (0.00%)		
occurrences (all)	0		
Irritability- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 149 (0.00%)		
occurrences (all)	0		
Increased sleep- Infant Series Dose 1 / After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	14 / 131 (10.69%)		
occurrences (all)	14		
Increased sleep- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	0 / 149 (0.00%) 0		
Increased sleep- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[17] occurrences (all)	0 / 149 (0.00%) 0		
Decreased sleep- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[18] occurrences (all)	9 / 131 (6.87%) 9		
Decreased sleep- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	0 / 149 (0.00%) 0		
Decreased sleep- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	0 / 149 (0.00%) 0		
Hives (urticaria)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[21]	0 / 149 (0.00%)		
occurrences (all)	0		
Hives (urticaria)- Infant Series Dose 1/After Infant Series Dose 1/Toddler Dose/After Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	1 / 131 (0.76%)		
occurrences (all)	1		
Hives (urticaria)- Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 149 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Allergy to arthropod bite			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Milk allergy			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Allergy to animal			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Anaphylactic reaction			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			

Rhinitis allergic			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Infantile asthma			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Rhinitis perennial			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Excoriation			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Joint dislocation			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		

Thermal burn subjects affected / exposed occurrences (all)	2 / 149 (1.34%) 2		
Arthropod bite subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Wound subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Arthropod sting subjects affected / exposed occurrences (all)	1 / 149 (0.67%) 1		
Face injury subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Fall subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Lip injury subjects affected / exposed occurrences (all)	1 / 149 (0.67%) 1		
Cardiac disorders Wolff-Parkinson-White syndrome subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Blood and lymphatic system disorders Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	2 / 149 (1.34%) 2		
Eye discharge subjects affected / exposed occurrences (all)	2 / 149 (1.34%) 2		
Keratitis			

subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Ocular hyperaemia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	2 / 149 (1.34%)		
occurrences (all)	2		
Haematochezia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Ileus			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Inguinal hernia			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Intussusception			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		

Stomatitis			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Aphthous stomatitis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	5 / 149 (3.36%)		
occurrences (all)	5		
Eczema infantile			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Dermatitis diaper			
subjects affected / exposed	4 / 149 (2.68%)		
occurrences (all)	4		
Asteatosis			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Heat rash			
subjects affected / exposed	1 / 149 (0.67%)		
occurrences (all)	1		
Dermatitis atopic			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	0 / 149 (0.00%)		
occurrences (all)	0		
Erythema			

subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Rash generalised				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Urticaria				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Petechiae				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Rash				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Generalised erythema				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Dermal cyst				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Eczema asteatotic				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Erythema (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Dictionary version was not captured, hence 0.0 is mentioned.			
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic				
subjects affected / exposed[24]	0 / 122 (0.00%)			
occurrences (all)	0			

Erythema (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 149 (0.00%)		
occurrences (all)	0		
Erythema (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	43 / 134 (32.09%)		
occurrences (all)	43		
Erythema (Mild)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 149 (0.00%)		
occurrences (all)	0		
Erythema (Mild)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 122 (0.00%)		
occurrences (all)	0		
Erythema (Mild)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	36 / 133 (27.07%)		
occurrences (all)	36		
Erythema (Moderate)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[30]	0 / 149 (0.00%)		
occurrences (all)	0		
Erythema (Moderate)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 149 (0.00%)		
occurrences (all)	0		
Erythema (Moderate)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	13 / 131 (9.92%)		
occurrences (all)	13		
Induration (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 149 (0.00%)		
occurrences (all)	0		
Induration (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 149 (0.00%)		
occurrences (all)	0		
Induration (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	37 / 134 (27.61%)		
occurrences (all)	37		
Induration (Mild)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[36] occurrences (all)	0 / 149 (0.00%) 0		
Induration (Mild)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	0 / 149 (0.00%) 0		
Induration (Mild)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	33 / 133 (24.81%) 33		
Induration (Moderate)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	0 / 149 (0.00%) 0		
Induration (Moderate)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[40] occurrences (all)	0 / 149 (0.00%) 0		
Induration (Moderate)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[41]	13 / 131 (9.92%)		
occurrences (all)	13		
Tenderness (Any)- Infant Series Dose 1 / After Infant Series Dose 1 / Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 149 (0.00%)		
occurrences (all)	0		
Tenderness (Any)- Infant Series Dose 2 / After Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 149 (0.00%)		
occurrences (all)	0		
Tenderness (Any)- Infant Series Dose 3 / After Toddler Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	9 / 132 (6.82%)		
occurrences (all)	9		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	42 / 149 (28.19%)		
occurrences (all)	44		
Upper respiratory tract infection			
subjects affected / exposed	10 / 149 (6.71%)		
occurrences (all)	10		
Gastroenteritis			
subjects affected / exposed	8 / 149 (5.37%)		
occurrences (all)	8		
Bronchitis			
subjects affected / exposed	9 / 149 (6.04%)		
occurrences (all)	9		
Influenza			

subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Exanthema subitum				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	4			
Gastroenteritis viral				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Varicella				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Otitis media				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Impetigo				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Bronchiolitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Otitis media acute				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Pharyngitis				
subjects affected / exposed	4 / 149 (2.68%)			
occurrences (all)	4			
Enteritis infectious				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	1 / 149 (0.67%)			
occurrences (all)	1			
Gastroenteritis rotavirus				

subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Molluscum contagiosum				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus bronchitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Adenovirus infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Cellulitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Conjunctivitis viral				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Croup infectious				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Fungal skin infection				

subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Genital candidiasis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Hand-foot-and-mouth disease				
subjects affected / exposed	2 / 149 (1.34%)			
occurrences (all)	2			
Mucocutaneous candidiasis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Hordeolum				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Rotavirus infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Staphylococcal scalded skin syndrome				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Vaccination site infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			
Viral rash				
subjects affected / exposed	0 / 149 (0.00%)			
occurrences (all)	0			

Gastroenteritis bacterial subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Candidiasis subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Conjunctivitis bacterial subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Herpangina subjects affected / exposed occurrences (all)	1 / 149 (0.67%) 1		
Herpes simplex subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Localised infection subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Otitis media bacterial subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Candida nappy rash subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Bronchopneumonia subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		
Acute sinusitis subjects affected / exposed occurrences (all)	1 / 149 (0.67%) 1		
Gastroenteritis adenovirus subjects affected / exposed occurrences (all)	1 / 149 (0.67%) 1		
Metabolism and nutrition disorders Lactose intolerance			

subjects affected / exposed occurrences (all)	0 / 149 (0.00%) 0		

Notes:

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

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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for all days.
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[31] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[32] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

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

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

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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported