Clinical trial results:
A Phase 3, Randomized, Active-Controlled, Double-Blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine Given With DTaP Compared to Open-Label DTaP in Healthy Japanese Infants

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

Summary

EudraCT number	2014-004181-21
Trial protocol	Outside EU/EEA
Global end of trial date	30 November 2011

Results information

Result version number	v2 (current)
This version publication date	29 July 2016
First version publication date	24 July 2015
Version creation reason	• Correction of full data set reporting periods and duplicate AEs in their data

Trial information

Trial identification

Sponsor protocol code	6096A1-3024

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01200368
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851056

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	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	07 March 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 November 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immune responses to the 13 pneumococcal conjugates (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) induced by 13-valent pneumococcal conjugate vaccine (13vPnC) are non-inferior to the immune responses induced by 7-valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the infant series.
To assess whether the immune responses as measured by serum antibody responses to diphtheria toxoid, tetanus toxoid, pertussis toxoid (PT), and filamentous hemagglutinin (FHA) induced by diphtheria, tetanus, and acellular pertussis vaccine (DTaP) given with 13vPnC are comparable to the immune responses induced by DTaP given alone when measured 1 month after the infant series.
To evaluate the acceptability of the safety profile of 13vPnC and 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 Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 September 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: 551
Worldwide total number of subjects	551
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)	551
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:

Study conducted in Japan from 24 September 2010 to 30 November 2011. Total 551 subjects were enrolled and randomized in three groups (13vPnC+DTaP, 7vPnC+DTaP and DTaP [Catch-up 7vPnC]) however only 549 were vaccinated. Two subjects were randomized to DTaP (Catch-up 7vPnC) and 7vPnC+DTaP respectively, but never vaccinated.

Period 1

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

Arms

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

Arm description:

Subjects at 3 to 6 months of age received a single dose of 13vPnC subcutaneously followed by 2 single doses of 13vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.

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

Dosage and administration details:

Subjects at 3 to 6 months of age received a single 0.5 milliliter (mL) dose of 13vPnC subcutaneously followed by 2 single 0.5 mL doses of 13vPnC 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 concomitantly with each 13vPnC dose.

Arm title	7vPnC + DTaP 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	Active comparator
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for 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 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 concomitantly with each 7vPnC dose.

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).

Arm type	Active comparator
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 DTaP dose subcutaneously followed by 2 single 0.5 mL DTaP doses subcutaneously, 4 to 8 weeks after each previous dose (infant series).

Number of subjects in period 1	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series
Started	183	184	184
Vaccinated Dose 1	183	183	183
Vaccinated Dose 2	183	182	183
Vaccinated Dose 3	181	178	182
Completed	180	178	178
Not completed	3	6	6
Consent withdrawn by subject	-	2	2
Did not meet entrance criteria	-	1	-
Adverse Event	2	2	3
Unspecified	1	-	-
Randomized, not vaccinated	-	1	1

Period 2

Period 2 title	After Infant Series
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind

Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC + DTaP After Infant Series

Arm description:

Included subjects who received a single dose of 13vPnC at 3 to 6 months of age subcutaneously followed by 2 single doses of 13vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC + DTaP After Infant Series

Arm description:

Included subjects who received a single dose of 7vPnC at 3 to 6 months of age 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 Infant Series

Arm description:

Included subjects who received 4 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	Active comparator
Investigational medicinal product name	7vPnC (CU)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 2	13vPnC + DTaP After Infant Series	7vPnC + DTaP After Infant Series	DTaP (Catch-up 7vPnC) After Infant Series
Started	180	178	178
Completed	162	162	169
Not completed	18	16	9
Consent withdrawn by subject	10	8	4
Adverse Event	6	6	3
Unspecified	1	2	2
Lost to follow-up	1	-	-

Period 3

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC + DTaP Toddler Series

Arm description:

Subjects received a single dose of 13vPnC subcutaneously at 12 to 15 months of age (toddler dose). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.

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

Dosage and administration details:

Subjects received a single 0.5 mL dose of 13vPnC 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 concomitantly with each 13vPnC dose.

Arm title	7vPnC + DTaP Toddler Series

Arm description:

Subjects received 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	Active comparator
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 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 concomitantly with each 7vPnC dose.

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

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	Active comparator
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).

Investigational medicinal product name	7vPnC (CU)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 2 single CU doses of 7vPnC (Prevenar) were administered subcutaneously, 4 to 6 weeks post-toddler dose.

Number of subjects in period 3	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series	DTaP (Catch-up 7vPnC) Toddler Series
Started	162	162	169
Completed	162	159	168
Not completed	0	3	1
Adverse Event	-	3	1

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC + DTaP Infant Series
Reporting group description:	
Subjects at 3 to 6 months of age received a single dose of 13vPnC subcutaneously followed by 2 single doses of 13vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.	
Reporting group title	7vPnC + DTaP 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) 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).	

Reporting group values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series
Number of subjects	183	184	184
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	4.1	4.1	4.2
standard deviation	± 0.97	± 0.97	± 0.96
Gender categorical Units: Subjects			
Female	87	91	91
Male	96	93	93

Reporting group values	Total		
Number of subjects	551		
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	269		
Male	282		

End points

End points reporting groups

Reporting group title	13vPnC + DTaP Infant Series
Reporting group description:	
Subjects at 3 to 6 months of age received a single dose of 13vPnC subcutaneously followed by 2 single doses of 13vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.	
Reporting group title	7vPnC + DTaP 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) 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).	
Reporting group title	13vPnC + DTaP After Infant Series
Reporting group description:	
Included subjects who received a single dose of 13vPnC at 3 to 6 months of age subcutaneously followed by 2 single doses of 13vPnC subcutaneously, 4 to 8 weeks after each previous dose (infant series). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.	
Reporting group title	7vPnC + DTaP After Infant Series
Reporting group description:	
Included subjects who received a single dose of 7vPnC at 3 to 6 months of age 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 Infant Series
Reporting group description:	
Included subjects who received 4 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	13vPnC + DTaP Toddler Series
Reporting group description:	
Subjects received a single dose of 13vPnC subcutaneously at 12 to 15 months of age (toddler dose). A single dose of DTaP subcutaneously administered concomitantly with each 13vPnC dose.	
Reporting group title	7vPnC + DTaP Toddler Series
Reporting group description:	
Subjects received 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 Series
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 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[1]
End point description:	
Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95 percentage (%) confidence interval (CI) for the 7 common pneumococcal serotypes	

(serotypes 4, 6B, 9V, 14, 18C, 19F and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. To demonstrate non-inferiority, for 6 additional serotypes in 7vPnC + DTaP group, the lowest response observed among the 7 common serotypes in the group was taken as reference. 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 and determinate assay result after Dose 3 for the proposed analysis, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

Notes:

[1] - 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 analyzed for these two reporting arms (13vPnC + DTaP Infant Series a nd 7vPnC + DTaP Infant Series) only.

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	176		
Units: Percentage of Subjects				
number (confidence interval 95%)				
Serotype 4	100 (97.9 to 100)	100 (97.9 to 100)		
Serotype 6B	97.7 (94.3 to 99.4)	99.4 (96.9 to 100)		
Serotype 9V	100 (97.9 to 100)	100 (97.9 to 100)		
Serotype 14	100 (97.9 to 100)	100 (97.9 to 100)		
Serotype 18C	100 (97.9 to 100)	100 (97.9 to 100)		
Serotype 19F	98.9 (96 to 99.9)	96.6 (92.7 to 98.7)		
Serotype 23F	97.7 (94.3 to 99.4)	98.3 (95.1 to 99.6)		
Serotype 1	100 (97.9 to 100)	96.6 (92.7 to 98.7)		
Serotype 3	99.4 (96.9 to 100)	96.6 (92.7 to 98.7)		
Serotype 5	99.4 (96.9 to 100)	96.6 (92.7 to 98.7)		
Serotype 6A	98.3 (95.1 to 99.6)	96.6 (92.7 to 98.7)		
Serotype 7F	100 (97.9 to 100)	96.6 (92.7 to 98.7)		
Serotype 19A	100 (97.9 to 100)	96.6 (92.7 to 98.7)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	2.1

Notes:

[2] - Non-inferiority was declared if the lower confidence interval for the percent difference was greater than (>) -0.10.

Statistical analysis title	Serotype 6B

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Percent difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	1.1

Notes:

[3] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 9V

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.1

Notes:

[4] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 14
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.1

Notes:

[5] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.1

Notes:

[6] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Percent difference
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	6.3

Notes:

[7] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Percent difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	2.9

Notes:

[8] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 1
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Percent difference
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	7.3

Notes:

[9] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 3
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series

Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Parameter estimate	Percent difference
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	6.7

Notes:

[10] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 5

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	Percent difference
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	6.7

Notes:

[11] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 6A

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
Parameter estimate	Percent difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	5.8

Notes:

[12] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 7F

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	Percent difference
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	7.3

Notes:

[13] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 19A

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
Parameter estimate	Percent difference
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	7.3

Notes:

[14] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Primary: Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody for 7 Common Serotypes 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody for 7 Common Serotypes 1 Month After the Infant Series[15]

End point description:

Antibody geometric mean concentration (GMC) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) are presented. GMC (13vPnC) 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 and determinate assay result after Dose 3 for the proposed analysis, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

Notes:

[15] - 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 analyzed for these two reporting arms (13vPnC + DTaP Infant Series a nd 7vPnC + DTaP Infant Series) only.

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	176		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	9.4 (8.48 to 10.41)	11.54 (10.51 to 12.67)		
Serotype 6B	4.5 (3.9 to 5.21)	5.71 (4.93 to 6.63)		
Serotype 9V	5.04 (4.52 to 5.62)	6.8 (6.15 to 7.52)		
Serotype 14	13.86 (12.16 to 15.8)	16.79 (15.03 to 18.76)		
Serotype 18C	5.3 (4.75 to 5.91)	7.26 (6.53 to 8.08)		
Serotype 19F	7.37 (6.43 to 8.46)	8.38 (7.17 to 9.8)		
Serotype 23F	3.64 (3.16 to 4.19)	4.53 (3.96 to 5.18)		

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[16]
Parameter estimate	GMC ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.94

Notes:

[16] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for the IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 6B

Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[17]
Parameter estimate	GMC ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.97

Notes:

[17] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 9V
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
Parameter estimate	GMC ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.86

Notes:

[18] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 14
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
Parameter estimate	GMC ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.98

Notes:

[19] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 18C
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
Parameter estimate	GMC ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.85

Notes:

[20] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 19F
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[21]
Parameter estimate	GMC ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.08

Notes:

[21] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 23F
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[22]
Parameter estimate	GMC ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.98

Notes:

[22] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

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

End point description:

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 and determinate assay result after Dose 3 for the proposed analysis, and had no major protocol violations.

End point type	Primary

End point timeframe:

1 month after the infant series

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	177	176	175	
Units: Percentage of subjects				
number (confidence interval 95%)				
Diphtheria	99.4 (96.9 to 100)	96.6 (92.7 to 98.7)	100 (97.9 to 100)	
Tetanus	100 (97.9 to 100)	100 (97.9 to 100)	100 (97.9 to 100)	
Pertussis toxoid (PT)	99.4 (96.9 to 100)	96.6 (92.7 to 98.7)	100 (97.9 to 100)	
Filamentous hemagglutinin (FHA)	99.4 (96.9 to 100)	96.6 (92.7 to 98.7)	100 (97.9 to 100)	

Statistical analyses

Statistical analysis title	Difference in percentage for diphtheria toxoid

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for diphtheria toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	DTaP (Catch-up 7vPnC) Infant Series v 13vPnC + DTaP Infant Series
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	other[23]
Parameter estimate	Percent difference
Point estimate	-0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	1.6

Notes:

[23] - The DTap response was summarized by descriptive.

Statistical analysis title	Difference in percentage for tetanus toxoid

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for tetanus toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	other[24]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.2

Notes:

[24] - The DTap response was summarized by descriptive.

Statistical analysis title	Difference in percentage for PT

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for pertussis toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	other[25]
Parameter estimate	Percent difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	1.6

Notes:

[25] - The DTap response was summarized by descriptive.

Statistical analysis title	Difference in percentage for FHA

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for filamentous hemagglutinin and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series

Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	other[26]
Parameter estimate	Percent difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	1.6

Notes:

[26] - The DTap response was summarized by descriptive.

Secondary: Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody for 6 Additional Serotypes 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) of Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody for 6 Additional Serotypes 1 Month After the Infant Series[27]

End point description:

Antibody GMC for 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. GMs were calculated using all subjects with available data for the specified blood draw. To demonstrate non-inferiority, for 6 additional serotypes in 7vPnC + DTaP group, the lowest GMC observed among the 7 common serotypes in the group was taken as reference. 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 and determinate assay result after Dose 3 for the proposed analysis, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the infant series

Notes:

[27] - 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 analyzed for these two reporting arms (13vPnC + DTaP Infant Series a nd 7vPnC + DTaP Infant Series) only.

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	176		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 1	8.14 (7.23 to 9.18)	4.53 (3.96 to 5.18)		
Serotype 3	4.9 (4.43 to 5.42)	4.53 (3.96 to 5.18)		
Serotype 5	4.64 (4.14 to 5.2)	4.53 (3.96 to 5.18)		
Serotype 6A	4.71 (4.15 to 5.34)	4.53 (3.96 to 5.18)		
Serotype 7F	8.26 (7.45 to 9.17)	4.53 (3.96 to 5.18)		

Serotype 19A	8.56 (7.67 to 9.56)	4.53 (3.96 to 5.18)		

Statistical analyses

Statistical analysis title	Serotype 1
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[28]
Parameter estimate	GMC ratio
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	2.15

Notes:

[28] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 3
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
Parameter estimate	GMC ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.28

Notes:

[29] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 5
Statistical analysis description:	
Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.	
Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series

Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[30]
Parameter estimate	GMC ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.22

Notes:

[30] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[31]
Parameter estimate	GMC ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.25

Notes:

[31] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[32]
Parameter estimate	GMC ratio
Point estimate	1.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.54
upper limit	2.16

Notes:

[32] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Infant Series v 7vPnC + DTaP Infant Series
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	non-inferiority[33]
Parameter estimate	GMC ratio
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.59
upper limit	2.25

Notes:

[33] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

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 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. To demonstrate non-inferiority, for 6 additional serotypes in 7vPnC + DTaP group, the lowest response observed among the 7 common serotypes in the group was taken as reference. Evaluable toddler immunogenicity set:eligible subjects who received vaccine to which they were randomized at all 4 doses,had blood drawn within specified time,had >=1 valid assay result after toddler dose for analysis,had no major protocol violation.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	158[34]	154[35]		
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 4	100 (97.7 to 100)	100 (97.6 to 100)		
Serotype 6B	100 (97.7 to 100)	100 (97.6 to 100)		
Serotype 9V	100 (97.7 to 100)	100 (97.6 to 100)		

Serotype 14	100 (97.7 to 100)	100 (97.6 to 100)		
Serotype 18C	100 (97.7 to 100)	100 (97.6 to 100)		
Serotype 19F	98.7 (95.5 to 99.8)	99.4 (96.4 to 100)		
Serotype 23F	100 (97.7 to 100)	100 (97.6 to 100)		
Serotype 1	99.4 (96.5 to 100)	99.4 (96.4 to 100)		
Serotype 3	99.4 (96.5 to 100)	99.4 (96.4 to 100)		
Serotype 5	100 (97.7 to 100)	99.4 (96.4 to 100)		
Serotype 6A	100 (97.7 to 100)	99.4 (96.4 to 100)		
Serotype 7F	100 (97.7 to 100)	99.4 (96.4 to 100)		
Serotype 19A	100 (97.7 to 100)	99.4 (96.4 to 100)		

Notes:

[34] - Subjects with determinate IgG antibody level to serotype.

[35] - Subjects with determinate IgG antibody level to serotype.

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[36]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.4

Notes:

[36] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 6B
Statistical analysis description:	
Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[37]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.4

Notes:

[37] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 9V

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[38]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.4

Notes:

[38] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 14

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[39]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.4

Notes:

[39] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 18C

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[40]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.4

Notes:

[40] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 19F

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[41]
Parameter estimate	Percent difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	2.4

Notes:

[41] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 23F

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[42]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.4

Notes:

[42] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 1

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[43]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	3

Notes:

[43] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 3

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[44]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	3

Notes:

[44] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 5

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[45]
Parameter estimate	Percent difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	3.6

Notes:

[45] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 6A

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[46]
Parameter estimate	Percent difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	3.6

Notes:

[46] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 7F

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[47]
Parameter estimate	Percent difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	3.6

Notes:

[47] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

Statistical analysis title	Serotype 19A

Statistical analysis description:

Difference ([13vPnC + DTaP] – [7vPnC + DTaP]) in proportions, expressed as a percentage presented along with exact 2-sided 95% CI. Difference in proportions was calculated using the serotype with the lowest proportion among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[48]
Parameter estimate	Percent difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	3.6

Notes:

[48] - Non-inferiority was declared if the lower confidence interval for the percent difference was >-0.10.

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 GMC as measured by mcg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% confidence intervals (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. To demonstrate non-inferiority, for 6 additional serotypes in 7vPnC + DTaP group, the lowest GMC observed among the 7 common serotypes in the group was taken as reference. Evaluable toddler immunogenicity set:eligible subjects who received vaccine to which they were randomized at all 4 doses,had blood drawn within specified time,had >=1 valid assay result after toddler dose for analysis,had no major protocol violation.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	158[49]	154[50]		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4	15.34 (13.23 to 17.79)	16.35 (14.19 to 18.83)		
Serotype 6B	17.05 (14.47 to 20.08)	13.91 (11.93 to 16.21)		
Serotype 9V	7 (6.11 to 8.03)	8.64 (7.54 to 9.89)		
Serotype 14	19.7 (17.69 to 21.93)	20.69 (18.25 to 23.47)		

Serotype 18C	8.1 (6.94 to 9.47)	9.88 (8.64 to 11.3)		
Serotype 19F	16.73 (14.2 to 19.71)	9.55 (8.11 to 11.26)		
Serotype 23F	8.64 (7.46 to 10.01)	10 (8.61 to 11.62)		
Serotype 1	13.96 (11.94 to 16.31)	8.64 (7.54 to 9.89)		
Serotype 3	2.48 (2.17 to 2.85)	8.64 (7.54 to 9.89)		
Serotype 5	11.1 (9.83 to 12.53)	8.64 (7.54 to 9.89)		
Serotype 6A	15.17 (13.31 to 17.3)	8.64 (7.54 to 9.89)		
Serotype 7F	10.9 (9.54 to 12.45)	8.64 (7.54 to 9.89)		
Serotype 19A	16.02 (14.07 to 18.25)	8.64 (7.54 to 9.89)		

Notes:

[49] - Subjects with determinate IgG antibody level to serotype.

[50] - Subjects with determinate IgG antibody level to serotype.

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description: Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[51]
Parameter estimate	GMC ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.15

Notes:

[51] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 6B
Statistical analysis description: Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.	
Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[52]
Parameter estimate	GMC ratio
Point estimate	1.23

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.53

Notes:

[52] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 9V

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[53]
Parameter estimate	GMC ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.98

Notes:

[53] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 14

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[54]
Parameter estimate	GMC ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.12

Notes:

[54] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 18C

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[55]
Parameter estimate	GMC ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.01

Notes:

[55] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 19F

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[56]
Parameter estimate	GMC ratio
Point estimate	1.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	2.21

Notes:

[56] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 23F

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[57]
Parameter estimate	GMC ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.07

Notes:

[57] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 1

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC

ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[58]
Parameter estimate	GMC ratio
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.31
upper limit	1.99

Notes:

[58] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 3

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[59]
Parameter estimate	GMC ratio
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	0.35

Notes:

[59] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 5

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[60]
Parameter estimate	GMC ratio
Point estimate	1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.54

Notes:

[60] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 6A

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[61]
Parameter estimate	GMC ratio
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	2.12

Notes:

[61] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 7F

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	7vPnC + DTaP Toddler Series v 13vPnC + DTaP Toddler Series
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[62]
Parameter estimate	GMC ratio
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.52

Notes:

[62] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

Statistical analysis title	Serotype 19A

Statistical analysis description:

Ratio of IgG GMCs ([13vPnC + DTaP]/[7vPnC + DTaP]) was calculated along with 2-sided 95% CI. GMC ratio was calculated using the serotype with the lowest GMC among the 7 common serotypes in the 7vPnC + DTaP group as reference.

Comparison groups	13vPnC + DTaP Toddler Series v 7vPnC + DTaP Toddler Series

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	non-inferiority[63]
Parameter estimate	GMC ratio
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.54
upper limit	2.24

Notes:

[63] - Non-inferiority was declared if the lower limit of the 2-sided, 95% CI for IgG GMC ratio was >0.5.

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:

Predefined antibody level was 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 population.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series	DTaP (Catch-up 7vPnC) Toddler Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	157[64]	154[65]	163[66]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Diphtheria	100 (97.7 to 100)	100 (97.6 to 100)	100 (97.8 to 100)	
Tetanus	100 (97.7 to 100)	100 (97.6 to 100)	100 (97.8 to 100)	
Pertussis toxoid (PT)	100 (97.7 to 100)	100 (97.6 to 100)	100 (97.8 to 100)	
Filamentous hemagglutinin (FHA)	100 (97.7 to 100)	100 (97.6 to 100)	100 (97.8 to 100)	

Notes:

[64] - Number of subjects with determinate DTaP antibody level to serotype.

[65] - Number of subjects with determinate DTaP antibody level to serotype.

[66] - Number of subjects with determinate DTaP antibody level to serotype.

Statistical analyses

Statistical analysis title	Diphtheria toxoid

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for diphtheria toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other[67]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.3

Notes:

[67] - The DTap response was summarized by descriptive.

Statistical analysis title	Tetanus toxoid

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for tetanus toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other[68]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.3

Notes:

[68] - The DTap response was summarized by descriptive.

Statistical analysis title	Pertussis toxoid

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for pertussis toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other[69]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.3

Notes:

[69] - The DTap response was summarized by descriptive.

Statistical analysis title	Filamentous hemagglutinin

Statistical analysis description:

Difference in percentage of subjects achieving predefined antibody levels for filamentous hemagglutinin and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	other[70]
Parameter estimate	Percent difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.3

Notes:

[70] - The DTap response was summarized by descriptive.

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

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

End point description:

GMC was measured in IU/mL and corresponding 2-sided 95% 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 and determinate assay result for the proposed analysis, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	177	176	175	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diphtheria	1.03 (0.94 to 1.12)	1.1 (0.97 to 1.25)	0.93 (0.86 to 1.02)	
Tetanus	1.5 (1.31 to 1.7)	1.37 (1.17 to 1.6)	1.66 (1.5 to 1.83)	

Statistical analyses

Statistical analysis title	Diphtheria toxoid
Statistical analysis description:	
GMC ratio for diphtheria toxoid and corresponding 2-sided 95% CI were calculated.	
Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.24

Statistical analysis title	Tetanus toxoid
Statistical analysis description:	
GMC ratio for tetanus toxoid and corresponding 2-sided 95% CI were calculated.	
Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.06

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

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

End point description:

GMC was 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 expected doses, had blood drawn within the protocol-specified time

frames, had at least 1 valid and determinate assay result for the proposed analysis, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after the infant series

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	177	176	175	
Units: EU/mL				
geometric mean (confidence interval 95%)				
PT	66.12 (60.45 to 72.32)	57.26 (49.23 to 66.6)	67.64 (62.87 to 72.78)	
FHA	62.3 (56.59 to 68.59)	53.86 (47.27 to 61.37)	67.48 (61.64 to 73.86)	

Statistical analyses

Statistical analysis title	GMC for Pertusis Toxoid

Statistical analysis description:

GMC ratio for PT and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.1

Statistical analysis title	GMC for Filamentous hemagglutinin

Statistical analysis description:

GMC ratio for FHA and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Infant Series v DTaP (Catch-up 7vPnC) Infant Series

Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.05

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:

GMC was measured in IU/mL and corresponding 2-sided 95% CI were evaluated for diphtheria and tetanus antibodies. Evaluable toddler immunogenicity population.

End point type	Secondary

End point timeframe:

1 month after the toddler dose

End point values	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series	DTaP (Catch-up 7vPnC) Toddler Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	157[71]	154[72]	163[73]	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diphtheria	2.65 (2.43 to 2.9)	3.18 (2.94 to 3.45)	2.63 (2.39 to 2.91)	
Tetanus	2.9 (2.56 to 3.28)	2.6 (2.29 to 2.95)	2.89 (2.58 to 3.25)	

Notes:

[71] - Number of subjects with determinate DTaP antibody level to serotype.

[72] - Number of subjects with determinate DTaP antibody level to serotype.

[73] - Number of subjects with determinate DTaP antibody level to serotype.

Statistical analyses

Statistical analysis title	Diphtheria toxoid

Statistical analysis description:

GMC ratio for diphtheria toxoid and corresponding 2-sided 95% CI were calculated.

Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series

Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.15

Statistical analysis title	Tetanus toxoid
Statistical analysis description:	
GMC ratio for tetanus toxoid and corresponding 2-sided 95% CI were calculated.	
Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.19

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:	
GMC was measured in EU/mL and corresponding 2-sided 95% CI were evaluated for PT and FHA antibodies. Evaluable toddler immunogenicity population.	
End point type	Secondary
End point timeframe:	
1 month after the toddler dose	

End point values	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series	DTaP (Catch-up 7vPnC) Toddler Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	157[74]	154[75]	163[76]	
Units: EU/mL				
geometric mean (confidence interval 95%)				

PT	144.46 (130.68 to 159.68)	135.65 (124.16 to 148.21)	150.21 (136.2 to 165.65)	
FHA	143.68 (130.94 to 157.66)	141.19 (129.2 to 154.3)	180.31 (163.12 to 199.32)	

Notes:

[74] - Number of subjects with determinate DTaP antibody level to serotype.

[75] - Number of subjects with determinate DTaP antibody level to serotype.

[76] - Number of subjects with determinate DTaP antibody level to serotype.

Statistical analyses

Statistical analysis title	GMC for Pertusis Toxoid
Statistical analysis description:	
GMC ratio for PT and corresponding 2-sided 95% CI were calculated.	
Comparison groups	DTaP (Catch-up 7vPnC) Toddler Series v 13vPnC + DTaP Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.11

Statistical analysis title	GMC for Filamentous hemagglutinin
Statistical analysis description:	
GMC ratio for FHA and corresponding 2-sided 95% CI were calculated.	
Comparison groups	13vPnC + DTaP Toddler Series v DTaP (Catch-up 7vPnC) Toddler Series
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMC ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.91

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). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population 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	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175[77]	174[78]	165[79]	
Units: Percentage of subjects				
number (not applicable)				
Redness- Any (n=171, 172, 165)	58.5	55.8	10.3	
Redness- Mild (n=170, 172, 165)	48.2	51.2	10.3	
Redness- Moderate (n=164, 166, 162)	18.9	18.1	0	
Redness- Severe (n=161, 162, 162)	0	0.6	0	
Swelling- Any (n=168, 168, 164)	41.1	35.7	4.9	
Swelling- Mild (n= 168, 168, 164)	38.1	31.5	4.9	
Swelling- Moderate (n=162, 165, 162)	12.3	12.7	0	
Swelling- severe (n=161, 162, 162)	0	0.6	0	
Tenderness- Any (n=163, 164, 162)	13.5	6.1	1.2	
Tenderness- Significant (n=161, 162, 162)	0	0	0	
Any local reaction (n=175, 174, 165)	68	60.9	12.1	

Notes:

[77] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[78] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[79] - 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). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population 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	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167[80]	173[81]	164[82]	
Units: Percentage of subjects				
number (not applicable)				
Redness- Any (n= 166, 168, 161)	62.7	61.9	36.6	
Redness- Mild (n= 166, 167, 161)	56	56.9	34.8	
Redness- Moderate (n= 157, 159, 156)	26.1	27	8.3	
Redness- Severe (n= 157, 154, 154)	0	0	0	
Swelling- Any (n= 160, 171, 162)	48.1	50.9	24.1	
Swelling- Mild (n= 160, 170, 162)	44.4	48.2	22.8	
Swelling- Moderate (n= 157, 157, 155)	19.7	17.8	5.8	
Swelling- severe (n= 157, 154, 154)	0	0	0	
Tenderness- Any (n= 159, 154, 155)	14.5	4.5	1.9	
Tenderness- Significant (n= 157, 154, 154)	0.6	0	0	
Any local reaction (n=167, 173, 164)	71.3	67.1	40.2	

Notes:

[80] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[81] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[82] - 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). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population 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	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	171[83]	163[84]	160[85]	
Units: Percentage of subjects				
number (not applicable)				
Redness- Any (n= 168, 162, 156)	53.6	51.2	23.1	
Redness- Mild (n= 167, 160, 156)	47.3	43.1	21.8	
Redness- Moderate (n= 152, 154, 153)	17.1	22.1	2	
Redness- Severe (n= 149, 152, 152)	0	0	0	
Swelling- Any (n= 164, 157, 159)	43.9	37.6	21.4	
Swelling- Mild (n= 164, 156, 159)	42.1	34	20.1	
Swelling- Moderate (n= 150, 154, 153)	10.7	14.9	2.6	
Swelling- severe (n= 149, 152, 152)	0	0	0	
Tenderness- Any (n= 153, 155, 153)	7.8	7.1	2.6	
Tenderness- Significant (n= 149, 152, 152)	0	0	0.7	
Any local reaction (n=171, 163, 160)	62	55.8	28.8	

Notes:

[83] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[84] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[85] - 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). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population 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	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series	DTaP (Catch-up 7vPnC) Toddler Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153[86]	152[87]	151[88]	
Units: Percentage of subjects				
number (not applicable)				
Redness- Any (n= 148, 152, 149)	62.2	57.2	34.9	
Redness- Mild (n= 148, 151, 148)	50	47.7	28.4	

Redness- Moderate (n= 141, 139, 145)	27.7	27.3	13.1	
Redness- Severe (n= 140, 136, 141)	0	0	0	
Swelling- Any (n= 149, 144, 148)	49	45.8	26.4	
Swelling- Mild (n= 147, 143, 146)	42.9	42	22.6	
Swelling- Moderate (n= 143, 138, 146)	16.8	18.8	13	
Swelling- severe (n= 140, 136, 141)	0	0	0	
Tenderness- Any (n= 142, 140 ,142)	14.1	10	5.6	
Tenderness- Significant (n= 140, 136, 141)	0.7	0	0	
Any local reaction (n=153, 152, 151)	68.6	61.8	37.1	

Notes:

[86] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[87] - Subjects reporting yes for at least 1 day or no for all days for any local reaction.

[88] - 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 specified systemic reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 1 of infant series

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	177[89]	174[90]	172[91]	
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5,=<39 degrees C (n=168, 168, 165)	36.3	33.9	21.8	
Fever >39,=<40 degrees C (n=161, 163, 162)	0.6	1.2	0.6	
Fever >40 degrees C (n=161, 162, 162)	0	0	0	
Decreased appetite (n=163, 163, 165)	12.9	9.2	7.3	
Irritability (n=165, 164, 164)	18.8	16.5	12.2	
Increased sleep (n=170, 165, 165)	28.8	26.7	21.8	
Decreased sleep (n=164, 169, 167)	18.3	21.3	13.8	
Hives- urticaria (n=161, 162, 162)	3.1	1.2	0	
Use of antipyretic medication (n= 161, 162, 162)	3.7	2.5	0.6	
Any systemic event (n=177, 174, 172)	61	59.8	43	

Notes:

[89] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[90] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[91] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

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 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 specified systemic reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 2 of infant series

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170[92]	169[93]	166[94]	
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5, =<39 degrees C (n=166, 161, 155)	36.7	36.6	21.9	
Fever >39, =<40 degrees C (n=158, 155, 154)	1.9	3.9	0.6	
Fever >40 degrees C (n=157, 154, 154)	0	0	0	
Decreased appetite (n=158, 159, 155)	11.4	14.5	7.1	
Irritability (n=162, 155, 156)	17.9	18.7	10.9	
Increased sleep (n=163, 158, 163)	22.7	22.2	22.7	
Decreased sleep (n=161, 157, 157)	18.6	12.1	12.1	
Hives- urticaria (n=157, 154, 154)	2.5	1.3	1.9	
Use of antipyretic medication (n=160, 155, 154)	3.1	4.5	1.3	
Any systemic event (n=170, 169, 166)	61.2	57.4	44.6	

Notes:

[92] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[93] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[94] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

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 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 specified systemic reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after Dose 3 of infant series

End point values	13vPnC + DTaP Infant Series	7vPnC + DTaP Infant Series	DTaP (Catch-up 7vPnC) Infant Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	168[95]	164[96]	159[97]	
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5, =<39 degrees C (n=162, 161, 157)	34.6	30.4	24.2	
Fever >39, =<40 degrees C (n=150, 152, 153)	3.3	2	3.3	
Fever >40 degrees C (n=149, 152, 152)	0	0.7	0	
Decreased appetite (n=152, 155, 154)	9.9	9.7	5.8	
Irritability (n=154, 156, 154)	17.5	14.7	11.7	
Increased sleep (n=151, 157, 154)	20.5	20.4	14.9	
Decreased sleep (n= 154, 156, 153)	18.2	12.8	9.8	
Hives- urticaria (n= 149, 152, 152)	1.3	0	1.3	
Use of antipyretic medication (n=150, 153, 154)	2	3.3	4.5	
Any systemic event (n=168, 164, 159)	57.7	50	40.9	

Notes:

[95] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[96] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[97] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

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 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 specified systemic reaction for each group, respectively.

End point type	Other pre-specified

End point timeframe:

Within 7 days after the toddler dose

End point values	13vPnC + DTaP Toddler Series	7vPnC + DTaP Toddler Series	DTaP (Catch-up 7vPnC) Toddler Series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	148[98]	152[99]	149[100]	
Units: Percentage of subjects				
number (not applicable)				
Fever >=37.5, =<39 degrees C (n=145, 146, 146)	49	49.3	31.5	
Fever >39, =<40 degrees C (n=141, 136, 141)	4.3	8.8	3.5	
Fever >40 degrees C (n=139, 137, 141)	1.4	2.2	0	
Decreased appetite (n=143, 141, 143)	19.6	19.9	9.8	
Irritability (n=143, 141, 144)	18.2	21.3	16.7	
Increased sleep (n=145, 142, 143)	18.6	17.6	16.1	
Decreased sleep (n=142, 137, 141)	12.7	9.5	11.3	
Hives- urticaria (n=140, 136, 141)	3.6	2.2	2.1	
Use of antipyretic medication (n=141, 138, 142)	7.1	9.4	4.2	
Any systemic event (n=148, 152, 149)	62.8	63.8	50.3	

Notes:

[98] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[99] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

[100] - Subjects reporting yes for at least 1 day or no for all days for any systemic reaction.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs: from signing of ICF through study completion. AEs: from signing of ICF to 28 days after infant series dose 3 (Groups 1, 2), 28 days after catch-up dose 2 (Group 3), 28 days after toddler dose (Groups 1, 2) and 28 days after catch-up dose 3 (Group 3)

Adverse event reporting additional description:

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). LRs and SEs were to be assessed only for infant series and toddler dose groups.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	13vPnC + DTaP - Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL doses of 13vPnC 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	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 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	13vPnC + DTaP - After the Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL doses of 13vPnC 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	7vPnC + DTaP - After the Infant Series

Reporting group description:

Subjects who received 3 single 0.5 mL doses of 13vPnC 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 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	13vPnC + DTaP - Toddler Dose

Reporting group description:

Subjects who received a single 0.5 mL dose of 13vPnC 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	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 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 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	13vPnC + DTaP - Infant Series	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 183 (2.73%)	8 / 183 (4.37%)	10 / 183 (5.46%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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			
Dacryostenosis congenital			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis cranial			

subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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
Ear and labyrinth disorders			
Deafness bilateral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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 viral			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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
Herpangina			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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
Mycoplasma infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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
Parotitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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
Rotavirus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC + DTaP - After the Infant Series	7vPnC + DTaP - After the Infant Series	DTaP (Catch-up 7vPnC) - After the Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 183 (7.10%)	15 / 183 (8.20%)	10 / 183 (5.46%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
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			
Dacryostenosis congenital			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	6 / 183 (3.28%)	5 / 183 (2.73%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis cranial			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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
Ear and labyrinth disorders			

Deafness bilateral			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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 / 183 (0.55%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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
Exanthema subitum			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (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
Gastroenteritis			

subjects affected / exposed	0 / 183 (0.00%)	3 / 183 (1.64%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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
Herpangina			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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
Mycoplasma infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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
Otitis media			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (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
Parotitis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (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 syncytial virus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (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
Rotavirus infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (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
Urinary tract infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC + DTaP - Toddler Dose	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler

			Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 162 (0.00%)	4 / 162 (2.47%)	2 / 169 (1.18%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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			
Dacryostenosis congenital			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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	0 / 162 (0.00%)	3 / 162 (1.85%)	1 / 169 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis cranial			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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
Ear and labyrinth disorders			
Deafness bilateral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (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
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 norovirus			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis rotavirus			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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
Herpangina			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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
Mycoplasma infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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
Parotitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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 infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (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	2 / 169 (1.18%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Thermal burn			

subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Dacryostenosis congenital			
subjects affected / exposed	0 / 169 (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 / 169 (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	2 / 169 (1.18%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Neuritis cranial			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness bilateral			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Muscular weakness				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchiolitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exanthema subitum				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				

subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpangina			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mycoplasma infection			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parotitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 169 (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 / 169 (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 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 169 (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	13vPnC + DTaP - Infant Series	7vPnC + DTaP - Infant Series	DTaP (Catch-up 7vPnC) - Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	177 / 183 (96.72%)	174 / 183 (95.08%)	172 / 183 (93.99%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Kawasaki's disease			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Application site erythema			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Injection site dermatitis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	0	5	0
Injection site erythema			
subjects affected / exposed	1 / 183 (0.55%)	4 / 183 (2.19%)	0 / 183 (0.00%)
occurrences (all)	2	7	0
Injection site induration			
subjects affected / exposed	1 / 183 (0.55%)	3 / 183 (1.64%)	0 / 183 (0.00%)
occurrences (all)	1	3	0
Injection site swelling			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	4 / 183 (2.19%)	5 / 183 (2.73%)	6 / 183 (3.28%)
occurrences (all)	4	5	6
Vaccination site induration			
subjects affected / exposed	0 / 183 (0.00%)	3 / 183 (1.64%)	0 / 183 (0.00%)
occurrences (all)	0	3	0
Vaccination site erythema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fever ≥37.5°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[1]	61 / 168 (36.31%)	57 / 168 (33.93%)	36 / 165 (21.82%)
occurrences (all)	61	57	36
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[2]	1 / 161 (0.62%)	2 / 163 (1.23%)	1 / 162 (0.62%)
occurrences (all)	1	2	1
Fever >40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 161 (0.00%)	0 / 162 (0.00%)	0 / 162 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[4]	21 / 163 (12.88%)	15 / 163 (9.20%)	12 / 165 (7.27%)
occurrences (all)	21	15	12
Irritability Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[5]	31 / 165 (18.79%)	27 / 164 (16.46%)	20 / 164 (12.20%)
occurrences (all)	31	27	20
Increased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[6]	49 / 170 (28.82%)	44 / 165 (26.67%)	36 / 165 (21.82%)
occurrences (all)	49	44	36
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	30 / 164 (18.29%) 30	36 / 169 (21.30%) 36	23 / 167 (13.77%) 23
Hives (urticaria) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	5 / 161 (3.11%) 5	2 / 162 (1.23%) 2	0 / 162 (0.00%) 0
Use of antipyretic medication to treat symptoms Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	6 / 161 (3.73%) 6	4 / 162 (2.47%) 4	1 / 162 (0.62%) 1
Fever ≥37.5°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	61 / 166 (36.75%) 61	59 / 161 (36.65%) 59	34 / 155 (21.94%) 34
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	3 / 158 (1.90%) 3	6 / 155 (3.87%) 6	1 / 154 (0.65%) 1
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[12]	18 / 158 (11.39%)	23 / 159 (14.47%)	11 / 155 (7.10%)
occurrences (all)	18	23	11
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[13]	29 / 162 (17.90%)	29 / 155 (18.71%)	17 / 156 (10.90%)
occurrences (all)	29	29	17
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[14]	37 / 163 (22.70%)	35 / 158 (22.15%)	37 / 163 (22.70%)
occurrences (all)	37	35	37
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[15]	30 / 161 (18.63%)	19 / 157 (12.10%)	19 / 157 (12.10%)
occurrences (all)	30	19	19
Hives (urticaria) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[16]	4 / 157 (2.55%)	2 / 154 (1.30%)	3 / 154 (1.95%)
occurrences (all)	4	2	3
Use of antipyretic medication to treat symptoms Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[17]	5 / 160 (3.13%)	7 / 155 (4.52%)	2 / 154 (1.30%)
occurrences (all)	5	7	2
Fever ≥37.5°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[18] occurrences (all)	56 / 162 (34.57%) 56	49 / 161 (30.43%) 49	38 / 157 (24.20%) 38
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	5 / 150 (3.33%) 5	3 / 152 (1.97%) 3	5 / 153 (3.27%) 5
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	0 / 149 (0.00%) 0	1 / 152 (0.66%) 1	0 / 152 (0.00%) 0
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[21] occurrences (all)	15 / 152 (9.87%) 15	15 / 155 (9.68%) 15	9 / 154 (5.84%) 9
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[22] occurrences (all)	27 / 154 (17.53%) 27	23 / 156 (14.74%) 23	18 / 154 (11.69%) 18
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[23]	31 / 151 (20.53%)	32 / 157 (20.38%)	23 / 154 (14.94%)
occurrences (all)	31	32	23
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	28 / 154 (18.18%)	20 / 156 (12.82%)	15 / 153 (9.80%)
occurrences (all)	28	20	15
Use of antipyretic medication to treat symptoms Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	3 / 150 (2.00%)	5 / 153 (3.27%)	7 / 154 (4.55%)
occurrences (all)	3	5	7
Immune system disorders			
Food allergy			
subjects affected / exposed	2 / 183 (1.09%)	2 / 183 (1.09%)	2 / 183 (1.09%)
occurrences (all)	2	2	2
Milk allergy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	0	2	0
Breast swelling			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Genital labial adhesions			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Posthitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Adenoidal hypertrophy			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	6 / 183 (3.28%)	3 / 183 (1.64%)	10 / 183 (5.46%)
occurrences (all)	7	5	11
Epistaxis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Fibrinous bronchitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	1	1	0
Infantile asthma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pulmonary artery stenosis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	1 / 183 (0.55%)
occurrences (all)	0	2	1
Rhinorrhoea			
subjects affected / exposed	5 / 183 (2.73%)	2 / 183 (1.09%)	2 / 183 (1.09%)
occurrences (all)	9	3	3
Investigations			
Body height below normal			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Chillblains			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Ear injury			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Excoriation			
subjects affected / exposed	1 / 183 (0.55%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	1	2	0
Fall			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	0	2	1
Head injury			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Scratch			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Frostbite			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Dacryostenosis congenita			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Nervous system disorders			
Neuritis cranial			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Conjunctivitis			
subjects affected / exposed	7 / 183 (3.83%)	11 / 183 (6.01%)	20 / 183 (10.93%)
occurrences (all)	9	13	23
Conjunctivitis allergic			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Eye discharge			
subjects affected / exposed	7 / 183 (3.83%)	5 / 183 (2.73%)	3 / 183 (1.64%)
occurrences (all)	9	5	4
Eye pruritus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Acetonaemic vomiting			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	2 / 183 (1.09%)	4 / 183 (2.19%)	3 / 183 (1.64%)
occurrences (all)	2	5	3
Diarrhoea			
subjects affected / exposed	10 / 183 (5.46%)	9 / 183 (4.92%)	5 / 183 (2.73%)
occurrences (all)	10	10	5
Dyspepsia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	1 / 183 (0.55%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	1	2	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	2 / 183 (1.09%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	2	1	0
Hives (urticaria) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	2 / 149 (1.34%)	0 / 152 (0.00%)	2 / 152 (1.32%)
occurrences (all)	2	0	2
Skin and subcutaneous tissue disorders			
Onychomadesis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Asteatosis			
subjects affected / exposed	8 / 183 (4.37%)	7 / 183 (3.83%)	5 / 183 (2.73%)
occurrences (all)	8	7	5
Dermatitis			
subjects affected / exposed	2 / 183 (1.09%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	2	0	1
Dermatitis atopic			
subjects affected / exposed	4 / 183 (2.19%)	0 / 183 (0.00%)	3 / 183 (1.64%)
occurrences (all)	4	0	3
Dermatitis contact			
subjects affected / exposed	4 / 183 (2.19%)	5 / 183 (2.73%)	5 / 183 (2.73%)
occurrences (all)	5	5	5
Dermatitis diaper			
subjects affected / exposed	16 / 183 (8.74%)	19 / 183 (10.38%)	26 / 183 (14.21%)
occurrences (all)	17	20	29
Dry skin			
subjects affected / exposed	7 / 183 (3.83%)	2 / 183 (1.09%)	5 / 183 (2.73%)
occurrences (all)	8	2	5
Eczema			
subjects affected / exposed	24 / 183 (13.11%)	26 / 183 (14.21%)	27 / 183 (14.75%)
occurrences (all)	25	34	30
Eczema asteatotic			

subjects affected / exposed	9 / 183 (4.92%)	8 / 183 (4.37%)	4 / 183 (2.19%)
occurrences (all)	11	8	4
Eczema infantile			
subjects affected / exposed	12 / 183 (6.56%)	7 / 183 (3.83%)	7 / 183 (3.83%)
occurrences (all)	13	8	7
Erythema			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	0	2	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Heat rash			
subjects affected / exposed	2 / 183 (1.09%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	2	1	0
Hyperkeratosis palmaris and plantaris			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Papule			
subjects affected / exposed	2 / 183 (1.09%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Rash generalised			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Scar			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1

Rash			
subjects affected / exposed	6 / 183 (3.28%)	2 / 183 (1.09%)	5 / 183 (2.73%)
occurrences (all)	7	2	6
Urticaria			
subjects affected / exposed	3 / 183 (1.64%)	5 / 183 (2.73%)	4 / 183 (2.19%)
occurrences (all)	3	5	4
Redness(Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	100 / 171 (58.48%)	96 / 172 (55.81%)	17 / 165 (10.30%)
occurrences (all)	100	96	17
Redness (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	82 / 170 (48.24%)	88 / 172 (51.16%)	17 / 165 (10.30%)
occurrences (all)	82	88	17
Redness (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	31 / 164 (18.90%)	30 / 166 (18.07%)	0 / 162 (0.00%)
occurrences (all)	31	30	0
Redness (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 161 (0.00%)	1 / 162 (0.62%)	0 / 162 (0.00%)
occurrences (all)	0	1	0
Swelling (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[31]	69 / 168 (41.07%)	60 / 168 (35.71%)	8 / 164 (4.88%)
occurrences (all)	69	168	164
Swelling (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	64 / 168 (38.10%)	53 / 168 (31.55%)	8 / 164 (4.88%)
occurrences (all)	64	53	8
Swelling (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	20 / 162 (12.35%)	21 / 165 (12.73%)	0 / 162 (0.00%)
occurrences (all)	20	21	0
Swelling (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 161 (0.00%)	1 / 162 (0.62%)	0 / 162 (0.00%)
occurrences (all)	0	1	0
Tenderness (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	22 / 163 (13.50%)	10 / 164 (6.10%)	2 / 162 (1.23%)
occurrences (all)	22	10	2
Tenderness (Significant) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 161 (0.00%)	0 / 162 (0.00%)	0 / 162 (0.00%)
occurrences (all)	0	0	0
Redness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	104 / 166 (62.65%) 104	104 / 168 (61.90%) 104	59 / 161 (36.65%) 59
Redness (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	93 / 166 (56.02%) 93	95 / 167 (56.89%) 95	56 / 161 (34.78%) 56
Redness (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	41 / 157 (26.11%) 41	43 / 159 (27.04%) 43	13 / 156 (8.33%) 13
Swelling (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[40] occurrences (all)	77 / 160 (48.13%) 77	87 / 171 (50.88%) 87	39 / 162 (24.07%) 39
Swelling (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 subjects affected / exposed[41] occurrences (all)	71 / 160 (44.38%) 71	82 / 170 (48.24%) 82	37 / 162 (22.84%) 37
Swelling (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	31 / 157 (19.75%) 31	28 / 157 (17.83%) 28	9 / 155 (5.81%) 9
Tenderness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[43] occurrences (all)	23 / 159 (14.47%) 23	7 / 154 (4.55%) 7	3 / 155 (1.94%) 3
Tenderness (Significant) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[44] occurrences (all)	1 / 157 (0.64%) 1	0 / 154 (0.00%) 0	0 / 154 (0.00%) 0
Redness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[45] occurrences (all)	90 / 168 (53.57%) 90	83 / 162 (51.23%) 83	36 / 156 (23.08%) 36
Redness (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[46] occurrences (all)	79 / 167 (47.31%) 79	69 / 160 (43.13%) 69	34 / 156 (21.79%) 34
Redness (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[47] occurrences (all)	26 / 152 (17.11%) 26	34 / 154 (22.08%) 34	3 / 153 (1.96%) 3
Swelling (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed[48]	72 / 164 (43.90%)	59 / 157 (37.58%)	34 / 159 (21.38%)
occurrences (all)	72	59	34
Swelling (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[49]	69 / 164 (42.07%)	53 / 156 (33.97%)	32 / 159 (20.13%)
occurrences (all)	69	53	32
Swelling (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[50]	16 / 150 (10.67%)	23 / 154 (14.94%)	4 / 153 (2.61%)
occurrences (all)	16	23	4
Tenderness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[51]	12 / 153 (7.84%)	11 / 155 (7.10%)	4 / 153 (2.61%)
occurrences (all)	12	11	4
Tenderness (Significant) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[52]	0 / 149 (0.00%)	0 / 152 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Vesicoureteric reflux			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
Acute sinusitis			
subjects affected / exposed	2 / 183 (1.09%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	2	1	2
Adenoviral conjunctivitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	1	1	0
Adenovirus infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	0	1	1
Anal abscess			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Anal fungal infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	2 / 183 (1.09%)	2 / 183 (1.09%)	5 / 183 (2.73%)
occurrences (all)	2	2	5
Bronchitis			
subjects affected / exposed	24 / 183 (13.11%)	28 / 183 (15.30%)	26 / 183 (14.21%)
occurrences (all)	40	43	36
Candidiasis			
subjects affected / exposed	1 / 183 (0.55%)	2 / 183 (1.09%)	1 / 183 (0.55%)
occurrences (all)	1	2	1
Conjunctivitis bacterial			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	1	1	1
Conjunctivitis infective			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis viral			

subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Croup infectious			
subjects affected / exposed	3 / 183 (1.64%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	3	1	0
Enteritis infectious			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	4 / 183 (2.19%)
occurrences (all)	1	1	5
Echo virus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
subjects affected / exposed	10 / 183 (5.46%)	17 / 183 (9.29%)	19 / 183 (10.38%)
occurrences (all)	10	17	19
Folliculitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	28 / 183 (15.30%)	24 / 183 (13.11%)	31 / 183 (16.94%)
occurrences (all)	30	26	38
Gastroenteritis norovirus			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	2 / 183 (1.09%)
occurrences (all)	1	1	2
Gastroenteritis viral			
subjects affected / exposed	7 / 183 (3.83%)	9 / 183 (4.92%)	7 / 183 (3.83%)
occurrences (all)	7	10	8
Genital infection fungal			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	1 / 183 (0.55%)
occurrences (all)	0	2	1
Hordeolum			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	0	2	0
Impetigo			

subjects affected / exposed	3 / 183 (1.64%)	3 / 183 (1.64%)	2 / 183 (1.09%)
occurrences (all)	3	3	2
Influenza			
subjects affected / exposed	3 / 183 (1.64%)	4 / 183 (2.19%)	6 / 183 (3.28%)
occurrences (all)	3	4	6
Laryngitis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 183 (1.09%)	0 / 183 (0.00%)
occurrences (all)	0	2	0
Molluscum contagiosum			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	48 / 183 (26.23%)	58 / 183 (31.69%)	51 / 183 (27.87%)
occurrences (all)	72	90	74
Oral candidiasis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Oral fungal infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	1 / 183 (0.55%)	2 / 183 (1.09%)	1 / 183 (0.55%)
occurrences (all)	1	2	1
Otitis media			
subjects affected / exposed	8 / 183 (4.37%)	6 / 183 (3.28%)	7 / 183 (3.83%)
occurrences (all)	11	6	7
Otitis media acute			
subjects affected / exposed	0 / 183 (0.00%)	5 / 183 (2.73%)	3 / 183 (1.64%)
occurrences (all)	0	7	3
Perirectal abscess			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	3 / 183 (1.64%)	3 / 183 (1.64%)	2 / 183 (1.09%)
occurrences (all)	3	3	2
Pharyngotonsillitis			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pneumococcal bacteraemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	0	2	1
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Respiratory syncytial virus bronchitis			
subjects affected / exposed	2 / 183 (1.09%)	1 / 183 (0.55%)	2 / 183 (1.09%)
occurrences (all)	2	1	2
Respiratory syncytial virus infection			
subjects affected / exposed	9 / 183 (4.92%)	14 / 183 (7.65%)	4 / 183 (2.19%)
occurrences (all)	9	14	4
Respiratory tract infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	2 / 183 (1.09%)	3 / 183 (1.64%)	2 / 183 (1.09%)
occurrences (all)	2	3	2
Sinusitis			
subjects affected / exposed	2 / 183 (1.09%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	2	0	2
Skin candida			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	1	1	0

Skin infection			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	3 / 183 (1.64%)
occurrences (all)	1	1	4
Upper respiratory tract infection			
subjects affected / exposed	54 / 183 (29.51%)	67 / 183 (36.61%)	65 / 183 (35.52%)
occurrences (all)	78	102	109
Urinary tract infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Varicella			
subjects affected / exposed	4 / 183 (2.19%)	8 / 183 (4.37%)	4 / 183 (2.19%)
occurrences (all)	4	8	4
Viral infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Viral rash			
subjects affected / exposed	3 / 183 (1.64%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	3	0	2
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Gianotti-Crosti syndrome			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis bacterial			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Herpangina			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Streptococcal infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	1 / 183 (0.55%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	13vPnC + DTaP - After the Infant Series	7vPnC + DTaP - After the Infant Series	DTaP (Catch-up 7vPnC) - After the Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 183 (10.93%)	27 / 183 (14.75%)	147 / 183 (80.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Haematoma			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Kawasaki's disease			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Application site erythema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Injection site dermatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Injection site induration			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Injection site swelling			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	12 / 183 (6.56%)
occurrences (all)	0	0	13
Vaccination site induration			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Vaccination site swelling			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Fever ≥37.5°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[1] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[2] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Fever >40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[3] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Decreased appetite Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[4] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Irritability Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Increased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[6]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Hives (urticaria) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Use of antipyretic medication to treat symptoms Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fever ≥37.5°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[15] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Hives (urticaria) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Use of antipyretic medication to treat symptoms Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[17]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fever ≥37.5°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Use of antipyretic medication to treat symptoms Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Immune system disorders			
Food allergy subjects affected / exposed occurrences (all)	6 / 183 (3.28%) 6	3 / 183 (1.64%) 3	6 / 183 (3.28%) 6
Milk allergy subjects affected / exposed occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Reproductive system and breast disorders			
Balanoposthitis subjects affected / exposed occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Breast swelling subjects affected / exposed occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Genital labial adhesions subjects affected / exposed occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Posthitis			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	5 / 183 (2.73%)	6 / 183 (3.28%)	15 / 183 (8.20%)
occurrences (all)	5	6	16
Epistaxis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Fibrinous bronchitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Infantile asthma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Nasal obstruction			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery stenosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	3 / 183 (1.64%)
occurrences (all)	0	1	3
Rhinorrhoea			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Investigations			
Body height below normal			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

Arthropod sting			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Chillblains			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Ear injury			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Excoriation			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	3
Head injury			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Frostbite			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2

Congenital, familial and genetic disorders			
Dacryostenosis congenita			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Neuritis cranial			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	3 / 183 (1.64%)	3 / 183 (1.64%)	4 / 183 (2.19%)
occurrences (all)	3	3	4
Lymphadenopathy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	9 / 183 (4.92%)
occurrences (all)	0	0	11
Conjunctivitis allergic			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Eye pruritus			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Keratitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Acetonaemic vomiting			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 183 (1.64%)	0 / 183 (0.00%)	5 / 183 (2.73%)
occurrences (all)	3	0	6
Diarrhoea			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	5 / 183 (2.73%)
occurrences (all)	0	1	5
Dyspepsia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Hives (urticaria) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Onychomadesis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Asteatosis			
subjects affected / exposed	1 / 183 (0.55%)	3 / 183 (1.64%)	2 / 183 (1.09%)
occurrences (all)	1	3	2
Dermatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	3
Dermatitis atopic			
subjects affected / exposed	2 / 183 (1.09%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	2	1	1
Dermatitis contact			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Dermatitis diaper			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	19 / 183 (10.38%)
occurrences (all)	1	0	23
Dry skin			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	1 / 183 (0.55%)
occurrences (all)	0	1	1
Eczema			

subjects affected / exposed	1 / 183 (0.55%)	2 / 183 (1.09%)	17 / 183 (9.29%)
occurrences (all)	1	2	19
Eczema asteatotic			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	2 / 183 (1.09%)
occurrences (all)	0	1	2
Eczema infantile			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	4 / 183 (2.19%)
occurrences (all)	0	0	5
Erythema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	4 / 183 (2.19%)
occurrences (all)	0	0	4
Hyperkeratosis palmaris and plantaris			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Seborrhoeic dermatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	3
Urticaria			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	4 / 183 (2.19%)
occurrences (all)	0	0	4
Redness(Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is		

	mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[31] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Swelling (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[32] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Swelling (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[33] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Swelling (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[34] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Tenderness (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[35] occurrences (all)	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0	0 / 183 (0.00%) 0
Tenderness (Significant) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed[36]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
subjects affected / exposed[41]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[47]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[48]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[49]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[50]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[51]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[52]	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Vesicoureteric reflux subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Adenoviral conjunctivitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Anal abscess			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Anal fungal infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Bacterial infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Bronchitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	35 / 183 (19.13%)
occurrences (all)	0	0	44
Candidiasis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Conjunctivitis bacterial			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Conjunctivitis infective			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Enteritis infectious			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	5 / 183 (2.73%)
occurrences (all)	0	0	6
Echo virus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Exanthema subitum			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	22 / 183 (12.02%)
occurrences (all)	0	0	22
Folliculitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	30 / 183 (16.39%)
occurrences (all)	0	0	37
Gastroenteritis norovirus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	8 / 183 (4.37%)
occurrences (all)	0	0	9
Genital infection fungal			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Hordeolum			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	4 / 183 (2.19%)
occurrences (all)	0	0	4
Influenza			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	13 / 183 (7.10%)
occurrences (all)	0	0	13
Laryngitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	3
Nasopharyngitis			
subjects affected / exposed	1 / 183 (0.55%)	2 / 183 (1.09%)	42 / 183 (22.95%)
occurrences (all)	1	2	68
Oral candidiasis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	1 / 183 (0.55%)	0 / 183 (0.00%)	8 / 183 (4.37%)
occurrences (all)	1	0	10
Otitis media acute			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	7 / 183 (3.83%)
occurrences (all)	0	0	8
Perirectal abscess			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			

subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	6 / 183 (3.28%)
occurrences (all)	0	0	6
Pharyngotonsillitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pneumococcal bacteraemia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1

Skin candida			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	4 / 183 (2.19%)
occurrences (all)	0	0	4
Upper respiratory tract infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	62 / 183 (33.88%)
occurrences (all)	0	0	82
Urinary tract infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Varicella			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	3
Viral infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Genital candidiasis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 183 (0.55%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Gianotti-Crosti syndrome			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Gastroenteritis bacterial			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Herpangina			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Rotavirus infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Streptococcal infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 183 (0.00%)	0 / 183 (0.00%)	0 / 183 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC + DTaP - Toddler Dose	7vPnC + DTaP - Toddler Dose	DTaP (Catch-up 7vPnC) - Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	153 / 162 (94.44%)	152 / 162 (93.83%)	151 / 169 (89.35%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Kawasaki's disease			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Application site erythema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Injection site dermatitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	2 / 162 (1.23%)	1 / 162 (0.62%)	1 / 169 (0.59%)
occurrences (all)	2	1	1
Injection site induration			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Injection site swelling			
subjects affected / exposed	1 / 162 (0.62%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	1	1	0
Pyrexia			
subjects affected / exposed	3 / 162 (1.85%)	5 / 162 (3.09%)	2 / 169 (1.18%)
occurrences (all)	3	5	2
Vaccination site induration			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fever ≥37.5°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence		

	from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[1] occurrences (all)	71 / 145 (48.97%) 71	72 / 146 (49.32%) 72	46 / 146 (31.51%) 46
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[2] occurrences (all)	6 / 141 (4.26%) 6	12 / 136 (8.82%) 12	5 / 141 (3.55%) 5
Fever >40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[3] occurrences (all)	2 / 139 (1.44%) 2	3 / 137 (2.19%) 3	0 / 141 (0.00%) 0
Decreased appetite Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[4] occurrences (all)	28 / 143 (19.58%) 28	28 / 141 (19.86%) 28	14 / 143 (9.79%) 14
Irritability Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	26 / 143 (18.18%) 26	30 / 141 (21.28%) 30	24 / 144 (16.67%) 24
Increased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[6]	27 / 145 (18.62%)	25 / 142 (17.61%)	23 / 143 (16.08%)
occurrences (all)	27	25	23
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[7]	18 / 142 (12.68%)	13 / 137 (9.49%)	16 / 141 (11.35%)
occurrences (all)	18	13	16
Hives (urticaria) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[8]	5 / 140 (3.57%)	3 / 136 (2.21%)	3 / 141 (2.13%)
occurrences (all)	5	3	3
Use of antipyretic medication to treat symptoms Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[9]	10 / 141 (7.09%)	13 / 138 (9.42%)	6 / 142 (4.23%)
occurrences (all)	10	13	6
Fever ≥37.5°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[15] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Hives (urticaria) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Use of antipyretic medication to treat symptoms Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[17]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fever ≥37.5°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Use of antipyretic medication to treat symptoms Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Immune system disorders			
Food allergy subjects affected / exposed occurrences (all)	2 / 162 (1.23%) 2	0 / 162 (0.00%) 0	1 / 169 (0.59%) 1
Milk allergy subjects affected / exposed occurrences (all)	1 / 162 (0.62%) 1	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Reproductive system and breast disorders			
Balanoposthitis subjects affected / exposed occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Breast swelling subjects affected / exposed occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Genital labial adhesions subjects affected / exposed occurrences (all)	0 / 162 (0.00%) 0	0 / 162 (0.00%) 0	0 / 169 (0.00%) 0
Posthitis			

subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	1 / 162 (0.62%)	2 / 162 (1.23%)	0 / 169 (0.00%)
occurrences (all)	1	2	0
Epistaxis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fibrinous bronchitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Infantile asthma			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
Nasal obstruction			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Pulmonary artery stenosis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 162 (1.23%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	2	0	0
Investigations			
Body height below normal			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod sting			
subjects affected / exposed	2 / 162 (1.23%)	2 / 162 (1.23%)	1 / 169 (0.59%)
occurrences (all)	2	2	1
Arthropod bite			
subjects affected / exposed	1 / 162 (0.62%)	2 / 162 (1.23%)	5 / 169 (2.96%)
occurrences (all)	1	2	5
Chillblains			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Ear injury			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 162 (0.62%)	1 / 162 (0.62%)	2 / 169 (1.18%)
occurrences (all)	1	1	2
Head injury			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Frostbite			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Congenital, familial and genetic disorders			
Dacryostenosis congenita			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Neuritis cranial			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 162 (0.00%)	2 / 162 (1.23%)	2 / 169 (1.18%)
occurrences (all)	0	2	2
Lymphadenopathy			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear haemorrhage			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	2 / 162 (1.23%)	3 / 162 (1.85%)	2 / 169 (1.18%)
occurrences (all)	2	3	2
Conjunctivitis allergic			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			

subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Acetonaemic vomiting			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	2 / 169 (1.18%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	3 / 162 (1.85%)	3 / 162 (1.85%)	5 / 169 (2.96%)
occurrences (all)	3	3	5
Dyspepsia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Hives (urticaria) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Onychomadesis			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Asteatosis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	1 / 169 (0.59%)
occurrences (all)	0	1	1
Dermatitis diaper			
subjects affected / exposed	5 / 162 (3.09%)	6 / 162 (3.70%)	1 / 169 (0.59%)
occurrences (all)	5	6	1
Dry skin			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Eczema			

subjects affected / exposed	3 / 162 (1.85%)	5 / 162 (3.09%)	5 / 169 (2.96%)
occurrences (all)	3	5	5
Eczema asteatotic			
subjects affected / exposed	2 / 162 (1.23%)	0 / 162 (0.00%)	3 / 169 (1.78%)
occurrences (all)	2	0	3
Eczema infantile			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	5 / 162 (3.09%)	6 / 162 (3.70%)	5 / 169 (2.96%)
occurrences (all)	5	6	5
Hyperkeratosis palmaris and plantaris			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Seborrhoeic dermatitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 162 (1.23%)	3 / 162 (1.85%)	0 / 169 (0.00%)
occurrences (all)	2	3	0
Urticaria			
subjects affected / exposed	2 / 162 (1.23%)	2 / 162 (1.23%)	1 / 169 (0.59%)
occurrences (all)	3	2	1
Redness(Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	92 / 148 (62.16%)	87 / 152 (57.24%)	52 / 149 (34.90%)
occurrences (all)	92	87	52
Redness (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	74 / 148 (50.00%)	72 / 151 (47.68%)	42 / 148 (28.38%)
occurrences (all)	74	72	42
Redness (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	39 / 141 (27.66%)	38 / 139 (27.34%)	19 / 145 (13.10%)
occurrences (all)	39	38	19
Redness (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 140 (0.00%)	0 / 136 (0.00%)	0 / 141 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is		

	mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	73 / 149 (48.99%)	66 / 144 (45.83%)	39 / 148 (26.35%)
occurrences (all)	73	66	39
Swelling (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	63 / 147 (42.86%)	60 / 143 (41.96%)	33 / 146 (22.60%)
occurrences (all)	147	143	146
Swelling (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	24 / 143 (16.78%)	26 / 138 (18.84%)	19 / 146 (13.01%)
occurrences (all)	24	26	19
Swelling (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 140 (0.00%)	0 / 136 (0.00%)	0 / 141 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	20 / 142 (14.08%)	14 / 140 (10.00%)	8 / 142 (5.63%)
occurrences (all)	20	14	8
Tenderness (Significant) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[36]	1 / 140 (0.71%)	0 / 136 (0.00%)	0 / 141 (0.00%)
occurrences (all)	1	0	0
Redness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
subjects affected / exposed[41]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Redness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Redness (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[47]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[48]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[49]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[50]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[51]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[52]	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Vesicoureteric reflux subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Adenoviral conjunctivitis			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	3 / 169 (1.78%)
occurrences (all)	0	1	3
Adenovirus infection			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
Anal abscess			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Anal fungal infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	1 / 169 (0.59%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	8 / 162 (4.94%)	9 / 162 (5.56%)	13 / 169 (7.69%)
occurrences (all)	9	9	13
Candidiasis			
subjects affected / exposed	1 / 162 (0.62%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			

subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	1	0	1
Enteritis infectious			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	1	0	1
Echo virus infection			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Erythema infectiosum			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
subjects affected / exposed	6 / 162 (3.70%)	3 / 162 (1.85%)	3 / 169 (1.78%)
occurrences (all)	6	3	3
Folliculitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	3 / 162 (1.85%)	7 / 162 (4.32%)	5 / 169 (2.96%)
occurrences (all)	3	7	5
Gastroenteritis norovirus			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 162 (0.00%)	2 / 162 (1.23%)	1 / 169 (0.59%)
occurrences (all)	0	2	1
Genital infection fungal			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Hordeolum			

subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	1 / 162 (0.62%)	4 / 162 (2.47%)	4 / 169 (2.37%)
occurrences (all)	1	4	4
Influenza			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	32 / 162 (19.75%)	21 / 162 (12.96%)	28 / 169 (16.57%)
occurrences (all)	36	23	32
Oral candidiasis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	4 / 162 (2.47%)	4 / 162 (2.47%)	5 / 169 (2.96%)
occurrences (all)	4	5	5
Otitis media acute			
subjects affected / exposed	4 / 162 (2.47%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	4	0	1
Perirectal abscess			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			

subjects affected / exposed	4 / 162 (2.47%)	3 / 162 (1.85%)	2 / 169 (1.18%)
occurrences (all)	4	3	2
Pharyngotonsillitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Pneumococcal bacteraemia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	1 / 169 (0.59%)
occurrences (all)	0	1	1
Respiratory tract infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Skin candida			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	1 / 169 (0.59%)
occurrences (all)	1	0	1
Skin infection			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 162 (0.00%)	3 / 162 (1.85%)	2 / 169 (1.18%)
occurrences (all)	0	3	2
Upper respiratory tract infection			
subjects affected / exposed	20 / 162 (12.35%)	19 / 162 (11.73%)	28 / 169 (16.57%)
occurrences (all)	26	20	31
Urinary tract infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	2 / 162 (1.23%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	2	0	0
Viral infection			
subjects affected / exposed	1 / 162 (0.62%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	1	1	0
Viral rash			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Gianotti-Crosti syndrome			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis bacterial			
subjects affected / exposed	1 / 162 (0.62%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	1	0	0

Hand-foot-and-mouth disease			
subjects affected / exposed	21 / 162 (12.96%)	27 / 162 (16.67%)	21 / 169 (12.43%)
occurrences (all)	21	27	24
Herpangina			
subjects affected / exposed	4 / 162 (2.47%)	1 / 162 (0.62%)	6 / 169 (3.55%)
occurrences (all)	4	1	6
Rotavirus infection			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Streptococcal infection			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 162 (0.00%)	1 / 162 (0.62%)	0 / 169 (0.00%)
occurrences (all)	0	1	0
Omphalitis			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 162 (0.00%)	0 / 162 (0.00%)	0 / 169 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	DTaP (Catch-up 7vPnC) - After the Toddler Dose		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	105 / 169 (62.13%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		

Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Kawasaki's disease			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Application site erythema			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Injection site dermatitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Injection site induration			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Injection site swelling			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Vaccination site induration			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Vaccination site erythema			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Vaccination site swelling			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Fever ≥37.5°C but ≤39°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence		

	from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[1] occurrences (all)	0 / 169 (0.00%) 0
Fever >39°C but ≤40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[2] occurrences (all)	0 / 169 (0.00%) 0
Fever >40°C Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[3] occurrences (all)	0 / 169 (0.00%) 0
Decreased appetite Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[4] occurrences (all)	0 / 169 (0.00%) 0
Irritability Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	0 / 169 (0.00%) 0
Increased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic	

subjects affected / exposed[6]	0 / 169 (0.00%)		
occurrences (all)	0		
Decreased sleep Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 169 (0.00%)		
occurrences (all)	0		
Hives (urticaria) Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 169 (0.00%)		
occurrences (all)	0		
Use of antipyretic medication to treat symptoms Dose 1	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 169 (0.00%)		
occurrences (all)	0		
Fever ≥37.5°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 169 (0.00%)		
occurrences (all)	0		
Fever >39°C but ≤40°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 169 (0.00%)		
occurrences (all)	0		
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 169 (0.00%) 0		
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	0 / 169 (0.00%) 0		
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	0 / 169 (0.00%) 0		
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[15] occurrences (all)	0 / 169 (0.00%) 0		
Hives (urticaria) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	0 / 169 (0.00%) 0		
Use of antipyretic medication to treat symptoms Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[17]	0 / 169 (0.00%)		
occurrences (all)	0		
Fever ≥37.5°C but ≤39°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 169 (0.00%)		
occurrences (all)	0		
Fever >39°C but ≤40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 169 (0.00%)		
occurrences (all)	0		
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 169 (0.00%)		
occurrences (all)	0		
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 169 (0.00%)		
occurrences (all)	0		
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 169 (0.00%)		
occurrences (all)	0		
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	0 / 169 (0.00%) 0			
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.			
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	0 / 169 (0.00%) 0			
Use of antipyretic medication to treat symptoms Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.			
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	0 / 169 (0.00%) 0			
Immune system disorders				
Food allergy subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0			
Milk allergy subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0			
Reproductive system and breast disorders				
Balanoposthitis subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0			
Breast swelling subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0			
Genital labial adhesions subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0			
Posthitis				

subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Fibrinous bronchitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Infantile asthma			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Nasal obstruction			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Pulmonary artery stenosis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Investigations			
Body height below normal			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			

Arthropod sting				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Arthropod bite				
subjects affected / exposed	5 / 169 (2.96%)			
occurrences (all)	5			
Chillblains				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Ear injury				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Excoriation				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Head injury				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Joint dislocation				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Scratch				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Thermal burn				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Contusion				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Frostbite				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			

Congenital, familial and genetic disorders			
Dacryostenosis congenita			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Neuritis cranial			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Lymphadenopathy			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear haemorrhage			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	6 / 169 (3.55%)		
occurrences (all)	6		
Conjunctivitis allergic			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Dacryostenosis acquired			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Eye discharge			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Eye pruritus			

subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Keratitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Acetonaemic vomiting			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Cheilitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		

Stomatitis			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Hives (urticaria) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 169 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Onychomadesis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Asteatosis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Dermatitis atopic			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Dermatitis diaper			
subjects affected / exposed	5 / 169 (2.96%)		
occurrences (all)	5		
Dry skin			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Eczema			

subjects affected / exposed	5 / 169 (2.96%)			
occurrences (all)	5			
Eczema asteatotic				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Eczema infantile				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Haemorrhage subcutaneous				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Heat rash				
subjects affected / exposed	4 / 169 (2.37%)			
occurrences (all)	4			
Hyperkeratosis palmaris and plantaris				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Papule				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Pityriasis rosea				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Rash generalised				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Scar				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			

Seborrhoeic dermatitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	2 / 169 (1.18%)		
occurrences (all)	2		
Redness(Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is		

	mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Mild) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Moderate) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Severe) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 169 (0.00%)		
occurrences (all)	0		
Tenderness (Any) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 169 (0.00%)		
occurrences (all)	0		
Tenderness (Significant) Dose 1	Additional description: Dose 1: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[36]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Mild) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
subjects affected / exposed[41]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Moderate) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 169 (0.00%)		
occurrences (all)	0		
Tenderness (Any) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 169 (0.00%)		
occurrences (all)	0		
Tenderness (Significant) Dose 2	Additional description: Dose 2: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 169 (0.00%)		
occurrences (all)	0		
Redness (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[47]	0 / 169 (0.00%)		
occurrences (all)	0		
Swelling (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[48] occurrences (all)	0 / 169 (0.00%) 0		
Swelling (Mild) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[49] occurrences (all)	0 / 169 (0.00%) 0		
Swelling (Moderate) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[50] occurrences (all)	0 / 169 (0.00%) 0		
Tenderness (Any) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[51] occurrences (all)	0 / 169 (0.00%) 0		
Tenderness (Significant) Dose 3	Additional description: Dose 3: 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. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[52] occurrences (all)	0 / 169 (0.00%) 0		
Renal and urinary disorders			
Vesicoureteric reflux subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0		
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Adenoviral conjunctivitis			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Adenovirus infection			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Anal abscess			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Anal fungal infection			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Bacterial infection			
subjects affected / exposed	0 / 169 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	16 / 169 (9.47%)		
occurrences (all)	18		
Candidiasis			
subjects affected / exposed	2 / 169 (1.18%)		
occurrences (all)	2		
Conjunctivitis bacterial			
subjects affected / exposed	1 / 169 (0.59%)		
occurrences (all)	1		
Conjunctivitis infective			

subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Conjunctivitis viral				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Croup infectious				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Enteritis infectious				
subjects affected / exposed	2 / 169 (1.18%)			
occurrences (all)	2			
Echo virus infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Erythema infectiosum				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Exanthema subitum				
subjects affected / exposed	4 / 169 (2.37%)			
occurrences (all)	4			
Folliculitis				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	9 / 169 (5.33%)			
occurrences (all)	9			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Gastroenteritis viral				
subjects affected / exposed	2 / 169 (1.18%)			
occurrences (all)	2			
Genital infection fungal				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Hordeolum				

subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	2 / 169 (1.18%)			
occurrences (all)	2			
Influenza				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Molluscum contagiosum				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	27 / 169 (15.98%)			
occurrences (all)	30			
Oral candidiasis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Oral fungal infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	7 / 169 (4.14%)			
occurrences (all)	7			
Otitis media acute				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Perirectal abscess				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Pharyngitis				

subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Pharyngotonsillitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Pneumococcal bacteraemia				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Rash pustular				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus bronchitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				
subjects affected / exposed	2 / 169 (1.18%)			
occurrences (all)	2			
Respiratory tract infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			

Skin candida				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Skin infection				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Tonsillitis				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Upper respiratory tract infection				
subjects affected / exposed	25 / 169 (14.79%)			
occurrences (all)	28			
Urinary tract infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Varicella				
subjects affected / exposed	2 / 169 (1.18%)			
occurrences (all)	2			
Viral infection				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Viral rash				
subjects affected / exposed	1 / 169 (0.59%)			
occurrences (all)	1			
Gastroenteritis rotavirus				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Genital candidiasis				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Gianotti-Crosti syndrome				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			
Gastroenteritis bacterial				
subjects affected / exposed	0 / 169 (0.00%)			
occurrences (all)	0			

Hand-foot-and-mouth disease subjects affected / exposed occurrences (all)	7 / 169 (4.14%) 7		
Herpangina subjects affected / exposed occurrences (all)	2 / 169 (1.18%) 2		
Rotavirus infection subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0		
Streptococcal infection subjects affected / exposed occurrences (all)	1 / 169 (0.59%) 1		
Herpes simplex subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0		
Omphalitis subjects affected / exposed occurrences (all)	1 / 169 (0.59%) 1		
Oral herpes subjects affected / exposed occurrences (all)	1 / 169 (0.59%) 1		
Paronychia subjects affected / exposed occurrences (all)	1 / 169 (0.59%) 1		
Metabolism and nutrition disorders Lactose intolerance subjects affected / exposed occurrences (all)	0 / 169 (0.00%) 0		

Notes:

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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