

**Clinical trial results:****A Phase 3, Randomised, Active-controlled, Double-Blind Trial of the Safety, Tolerability and Immunologic Noninferiority of a 13-valent Pneumococcal Conjugate Vaccine Compared to a 7-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given in a 2-, 3-, 4- and 11- to 12-Months Schedule With Routine Pediatric Vaccinations.****Summary**

EudraCT number	2005-004770-24
Trial protocol	DE
Global end of trial date	26 August 2008

**Results information**

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	02 August 2015

**Trial information****Trial identification**

Sponsor protocol code	6096A1-006
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00366340
WHO universal trial number (UTN)	-

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., 1800 7181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 1800 7181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

**Paediatric regulatory details**

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000036-PIP01-07
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	11 September 2008
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	26 August 2008
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 7 common pneumococcal conjugates induced by 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 demonstrate that the immune responses to the 6 additional pneumococcal conjugates induced by 13-valent Pneumococcal Conjugate Vaccine (13vPnC) are non inferior to the lowest immune response, among the 7 common pneumococcal conjugates, induced by 7vPnC when measured 1 month after the infant series.
- To demonstrate that the immune responses induced by Infanrix hexa given with 13vPnC are noninferior to the immune responses induced by Infanrix hexa given with 7vPnC when measured 1 month after the infant series.

Safety objective:

- To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local injection site reactions, systemic events, and adverse events (AEs)

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 604
Worldwide total number of subjects	604
EEA total number of subjects	604

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	604
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Subjects were recruited in Germany from October 2006 to April 2007.

### Pre-assignment

Screening details:

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

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	13vPnC Infant Series

Arm description:

Subjects received one single dose of 13vPnC coadministered with combined Diphtheria-Tetanus-acellular Pertussis (DTPa), Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

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

Dosage and administration details:

0.5 milliliter (mL) dose of 13vPnC at 2, 3, 4 months (infant series)

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

Dosage and administration details:

Combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

<b>Arm title</b>	7vPnC Infant Series
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Arm description:

Subjects received one single dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

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

Dosage and administration details:

0.5 mL dose of 7vPnC at 2, 3, 4 months (infant series).

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

Dosage and administration details:

Combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

Number of subjects in period 1	13vPnC Infant Series	7vPnC Infant Series
Started	301	303
Vaccinated Dose 1	300	303
Vaccinated Dose 2	296	297
Vaccinated Dose 3	294	293
Completed	293	293
Not completed	8	10
Consent withdrawn by subject	3	3
Adverse Event	-	2
Protocol Violation	3	4
Lost to follow-up	1	1
Failure to return	1	-

## Period 2

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

## Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	13vPnC After the Infant Series

Arm description:

Included subjects who received of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3 and 4 months of age in the infant series.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

<b>Arm title</b>	7vPnC After the Infant Series
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Arm description:

Included subjects who received of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3 and 4 months of age in the infant series.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

<b>Number of subjects in period 2</b>	13vPnC After the Infant Series	7vPnC After the Infant Series
Started	293	293
Completed	290	287
Not completed	3	6
Failed to return	-	1
Adverse Event	-	1
Protocol Violation	2	2
Parent\legal guardian request	1	1
Lost to follow-up	-	1

### Period 3

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	13vPnC Toddler Dose

#### Arm description:

Subjects who received 13vPnC in the infant series, received one single 0.5 mL dose of 13vPnC co administered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose).

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

#### Dosage and administration details:

One single 0.5 mL dose of 13vPnC at 12 months of age (toddler dose).

Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose)

<b>Arm title</b>	7vPnC Toddler Dose
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Arm description:

Subjects who received 7vPnC in the infant series, received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose).

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

Dosage and administration details:

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

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

Dosage and administration details:

Combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series) and 12 months of age (toddler dose)

<b>Number of subjects in period 3</b>	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	290	287
Completed	289	286
Not completed	1	1
Failed to return	1	-
Parent\legal guardian request	-	1

## Baseline characteristics

### Reporting groups

Reporting group title	13vPnC Infant Series
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Reporting group description:

Subjects received one single dose of 13vPnC coadministered with combined Diphtheria-Tetanus-acellular Pertussis (DTPa), Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

Reporting group title	7vPnC Infant Series
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Reporting group description:

Subjects received one single dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

Reporting group values	13vPnC Infant Series	7vPnC Infant Series	Total
Number of subjects	301	303	604
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	2.5	2.5	
standard deviation	± 0.6	± 0.6	-
Gender categorical Units: Subjects			
Female	151	127	278
Male	150	176	326

## End points

### End points reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description: Subjects received one single dose of 13vPnC coadministered with combined Diphtheria-Tetanus-acellular Pertussis (DTPa), Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).	
Reporting group title	7vPnC Infant Series
Reporting group description: Subjects received one single dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).	
Reporting group title	13vPnC After the Infant Series
Reporting group description: Included subjects who received of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3 and 4 months of age in the infant series.	
Reporting group title	7vPnC After the Infant Series
Reporting group description: Included subjects who received of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3 and 4 months of age in the infant series.	
Reporting group title	13vPnC Toddler Dose
Reporting group description: Subjects who received 13vPnC in the infant series, received one single 0.5 mL dose of 13vPnC co administered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose).	
Reporting group title	7vPnC Toddler Dose
Reporting group description: Subjects who received 7vPnC in the infant series, received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose).	
Subject analysis set title	13vPnC Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2 months (infant series).	
Subject analysis set title	7vPnC Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2 months (infant series).	
Subject analysis set title	13vPnC Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 3 months (infant series).	
Subject analysis set title	7vPnC Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 3 months (infant series).	
Subject analysis set title	13vPnC Dose 3
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 4 months (infant series).

Subject analysis set title	7vPnC Dose 3
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 4 months (infant series).

Subject analysis set title	13vPnC Before Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

Subject analysis set title	7vPnC Before Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series).

Subject analysis set title	13vPnC After Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose).

Subject analysis set title	7vPnC After Toddler Dose
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 12 months of age (toddler dose)

Subject analysis set title	13vPnC Toddler dose
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series) and 12 months of age (toddler dose).

Subject analysis set title	7vPnC Toddler dose
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with combined DTPa, Hepatitis B, Poliovirus and Haemophilus influenzae type b vaccine (Infanrix hexa) at 2, 3, 4 months (infant series) and 12 months of age (toddler dose)

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**Primary: Percentage of Subjects Achieving Antibody Level greater than equal to ( $\geq$ ) 0.35 mcg/mL (microgram/milliliter) in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series**

End point title	Percentage of Subjects Achieving Antibody Level greater than equal to ( $\geq$ ) 0.35 mcg/mL (microgram/milliliter) in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series
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End point description:

Percentage of subjects achieving World Health Organization (WHO) predefined antibody threshold  $\geq$  0.35 mcg/mL along with the corresponding 95 percent confidence interval (% CI) for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
End point timeframe:	
One month after 3-dose infant series (5 months of age)	

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	279		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes-Serotype 4	77.5 (96 to 99.4)	98.2 (95.9 to 99.4)		
Common Serotypes-Serotype 6B	98.6 (72.2 to 82.2)	87.1 (82.5 to 90.8)		
Common Serotypes-Serotype 9V	98.9 (96.4 to 99.6)	96.4 (93.5 to 98.3)		
Common Serotypes-Serotype 14	97.2 (96.9 to 99.8)	97.5 (94.9 to 99)		
Common Serotypes-Serotype 18C	95.8 (94.5 to 98.8)	98.6 (96.3 to 99.6)		
Common Serotypes-Serotype 19F	88.7 (92.7 to 97.8)	96 (93 to 98)		
Common Serotypes-Serotype 23F	98.2 (84.5 to 92.2)	89.5 (85.3 to 92.9)		
Additional Serotypes-Serotype 1	96.1 (93.2 to 98.1)	1.4 (0.4 to 3.7)		
Additional Serotypes-Serotype 3	98.2 (95.9 to 99.4)	6.3 (3.7 to 9.8)		
Additional Serotypes-Serotype 5	93 (89.3 to 95.6)	31.6 (25.8 to 37.8)		
Additional Serotypes-Serotype 6A	91.9 (88.1 to 94.8)	31.6 (26.1 to 37.5)		
Additional Serotypes-Serotype 7F	98.6 (96.4 to 99.6)	4 (2 to 7)		
Additional Serotypes-Serotype 19A	99.3 (97.5 to 99.9)	79.2 (73.8 to 83.9)		

## Statistical analyses

<b>Statistical analysis title</b>	Serotype 4
Statistical analysis description:	
For serotype 4 the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[1]</sup>
Parameter estimate	Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.6

Notes:

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

<b>Statistical analysis title</b>	Serotype 6B
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Statistical analysis description:

For serotype 6B the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.

Comparison groups	7vPnC After the Infant Series v 13vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[2]</sup>
Parameter estimate	Difference
Point estimate	-9.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	-3.3

Notes:

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

<b>Statistical analysis title</b>	Serotype 9V
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Statistical analysis description:

For serotype 9V the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[3]</sup>
Parameter estimate	Difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	5.2

Notes:

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

<b>Statistical analysis title</b>	Serotype 14
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Statistical analysis description:

For serotype 14 the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
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Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[4]</sup>
Parameter estimate	Difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	4.1

Notes:

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

<b>Statistical analysis title</b>	Serotype 18C
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Statistical analysis description:

For serotype 18C the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[5]</sup>
Parameter estimate	Difference
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	1.2

Notes:

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

<b>Statistical analysis title</b>	Serotype 19F
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Statistical analysis description:

For serotype 19F the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[6]</sup>
Parameter estimate	Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	3.3

Notes:

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

<b>Statistical analysis title</b>	Serotype 23F
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Statistical analysis description:

For serotype 23F the difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[7]</sup>
Parameter estimate	Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	4.5

Notes:

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

### Primary: Geometric Mean Antibody Concentration in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series

End point title	Geometric Mean Antibody Concentration in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series
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End point description:

Antibody concentration/geometric mean concentration (GMC) as measured by enzyme-linked immunosorbent assay (ELISA) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC ratios (13vPnC/7vPnC) and corresponding 2-sided 95% CI were evaluated. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

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

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	279		
Units: Microgram/milliliter				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4	2.18 (1.98 to 2.4)	2.99 (2.68 to 3.33)		
Common Serotypes - Serotype 6B	0.98 (0.84 to 1.14)	1.49 (1.27 to 1.75)		
Common Serotypes - Serotype 9V	1.65 (1.51 to 1.8)	1.96 (1.77 to 2.17)		
Common Serotypes - Serotype 14	4.14 (3.68 to 4.66)	4.61 (4.07 to 5.23)		
Common Serotypes - Serotype 18C	1.94 (1.76 to 2.14)	2.25 (2.04 to 2.49)		
Common Serotypes - Serotype 19F	1.73 (1.56 to 1.92)	2.86 (2.53 to 3.24)		

Common Serotypes - Serotype 23F	1.26 (1.11 to 1.43)	1.44 (1.25 to 1.65)		
Additional Serotypes - Serotype 1	1.83 (1.64 to 2.04)	0.03 (0.02 to 0.03)		
Additional Serotypes - Serotype 3	1.55 (1.41 to 1.72)	0.05 (0.04 to 0.06)		
Additional Serotypes - Serotype 5	1.31 (1.17 to 1.46)	0.2 (0.18 to 0.23)		
Additional Serotypes - Serotype 6A	1.33 (1.18 to 1.49)	0.23 (0.2 to 0.26)		
Additional Serotypes - Serotype 7F	2.59 (2.36 to 2.85)	0.04 (0.04 to 0.05)		
Additional Serotypes - Serotype 19A	3.26 (2.97 to 3.59)	0.64 (0.58 to 0.71)		

## Statistical analyses

<b>Statistical analysis title</b>	Serotype 4
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Statistical analysis description:

For serotype 4 the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[8]</sup>
Parameter estimate	Ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.84

Notes:

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

<b>Statistical analysis title</b>	Serotype 6B
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Statistical analysis description:

For serotype 6B the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[9]</sup>
Parameter estimate	Ratio
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.82

Notes:

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

<b>Statistical analysis title</b>	Serotype 9V
Statistical analysis description: For serotype 9V the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[10]</sup>
Parameter estimate	Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.96

Notes:

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

<b>Statistical analysis title</b>	Serotype 14
Statistical analysis description: For serotype 14 the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[11]</sup>
Parameter estimate	Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.07

Notes:

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

<b>Statistical analysis title</b>	Serotype 18C
Statistical analysis description: For serotype 18C the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[12]</sup>
Parameter estimate	Ratio
Point estimate	0.86

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.99

Notes:

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

<b>Statistical analysis title</b>	Serotype 19F
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Statistical analysis description:

For serotype 19F the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[13]</sup>
Parameter estimate	Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.71

Notes:

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

<b>Statistical analysis title</b>	Serotype 23F
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Statistical analysis description:

For serotype 23F the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[14]</sup>
Parameter estimate	Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.06

Notes:

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

**Primary: Percentage of Subjects Achieving Antibody Titer  $\geq 1:8$  as Measured by Opsonophagocytic Activity Assay (OPA) in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series.**

End point title	Percentage of Subjects Achieving Antibody Titer $\geq 1:8$ as Measured by Opsonophagocytic Activity Assay (OPA) in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series. <sup>[15]</sup>
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End point description:

Percentage of Subjects achieving functional antibody titer  $\geq 1:8$  as measured by opsonophagocytic

activity assay (OPA) along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n)=number of subjects with a determinate postinfant series OPA antibody titer to the given serotype.

End point type	Primary
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End point timeframe:

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

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	279		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=92,94)	100 (96.1 to 100)	100 (96.2 to 100)		
Common Serotypes - Serotype 6B (n=100,94)	96 (90.1 to 98.9)	98.9 (94.2 to 100)		
Common Serotypes - Serotype 9V (n=89,89)	100 (95.9 to 100)	100 (95.9 to 100)		
Common Serotypes - Serotype 14 (n=95,89)	100 (96.2 to 100)	100 (95.9 to 100)		
Common Serotypes - Serotype 18C (n=100,94)	100 (96.4 to 100)	98.9 (94.2 to 100)		
Common Serotypes - Serotype 19F (n=100,94)	96 (90.1 to 98.9)	93.6 (86.6 to 97.6)		
Common Serotypes - Serotype 23F (n=100,93)	96 (90.1 to 98.9)	95.7 (89.4 to 98.8)		
Additional Serotypes - Serotype 1 (n=100,92)	93 (86.1 to 97.1)	4.3 (1.2 to 10.8)		
Additional Serotypes - Serotype 3 (n=100,94)	99 (94.6 to 100)	24.5 (16.2 to 34.4)		
Additional Serotypes - Serotype 5 (n=100,94)	99 (94.6 to 100)	4.3 (1.2 to 10.5)		
Additional Serotypes - Serotype 6A (n=99,93)	96 (90 to 98.9)	72 (61.8 to 80.9)		
Additional Serotypes - Serotype 7F (n=99,94)	100 (96.3 to 100)	78.7 (69.1 to 86.5)		
Additional Serotypes - Serotype 19A (n=95,94)	100 (96.2 to 100)	17 (10.1 to 26.2)		

## Statistical analyses

No statistical analyses for this end point

### Primary: Geometric Mean Antibody Titer in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series

End point title	Geometric Mean Antibody Titer in 13vPnC Group Relative to 7vPnC Group After the 3-Dose Infant Series <sup>[16]</sup>
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End point description:

Antibody functionality/geometric mean titer (GMT) as measured by opsonophagocytic activity assay (OPA) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity (per protocol) population of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n)= number of subjects with a determinate antibody titer for the specified serotype.

End point type	Primary
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End point timeframe:

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

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	279		
Units: titer				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=92,94)	1573.29 (205.52 to 305.89)	1860.79 (1540 to 2248.41)		
Common Serotypes - Serotype 6B (n=100,94)	744.43 (1283.03 to 1929.21)	1160.76 (921.46 to 1462.19)		
Common Serotypes - Serotype 9V (n=89,89)	4937.84 (556.91 to 995.11)	5379.51 (3935.51 to 7353.34)		
Common Serotypes - Serotype 14 (n=95,89)	2139.65 (3614.78 to 6745.14)	3345.19 (2473.27 to 4524.5)		
Common Serotypes - Serotype 18C (n=100,94)	1509.65 (1570.1 to 2915.79)	1780.26 (1382.42 to 2292.59)		
Common Serotypes - Serotype 19F (n=100,94)	150.12 (1243.64 to 1832.56)	165.69 (122.98 to 223.23)		
Common Serotypes - Serotype 23F (n=100,93)	1089.92 (116.89 to 192.81)	1070.83 (786.59 to 1457.78)		
Additional Serotypes - Serotype 1 (n=100,92)	50.21 (795.2 to 1493.86)	4.64 (3.96 to 5.43)		
Additional Serotypes - Serotype 3 (n=100,94)	250.73 (39.39 to 64.02)	6.13 (5.17 to 7.28)		
Additional Serotypes - Serotype 5 (n=100,94)	162.02 (126.31 to 207.82)	4.64 (3.96 to 5.43)		
Additional Serotypes - Serotype 6A (n=99,93)	1228.45 (883.49 to 1708.11)	122.4 (74.09 to 202.21)		
Additional Serotypes - Serotype 7F (n=99,94)	11544.75 (9364.02 to 14233.34)	115.45 (75.16 to 177.32)		
Additional Serotypes - Serotype 19A (n=95,94)	442.48 (360.53 to 543.06)	6.7 (5.19 to 8.66)		

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Achieving Predefined Antibody Levels for Haemophilus influenzae Type b, Diphtheria Toxoid, and Hepatitis B in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose

End point title	Percentage of Subjects Achieving Predefined Antibody Levels for Haemophilus influenzae Type b, Diphtheria Toxoid, and Hepatitis B in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose
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End point description:

Predefined Antibody Levels for Haemophilus Influenzae (HI) Type b (0.15 mcg/mL or 1.0 mcg/mL), for Diphtheria Toxoid (0.01 or 0.1 International units [IU]/mL) and for Hepatitis B ( $\geq 10.0$  milli international units/ milliliter (mIU/mL). Evaluable immunogenicity (per protocol) population of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after the infant series (5 months of age); one month after the toddler dose (13 months of age)

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	285 <sup>[17]</sup>	279 <sup>[18]</sup>	279 <sup>[19]</sup>	268 <sup>[20]</sup>
Units: percentage of subjects				
number (confidence interval 95%)				
HI type b 0.15 mcg/mL threshold	89.5 (85.2 to 92.9)	86.9 (82.1 to 90.8)	99.3 (98.5 to 100)	100 (98.5 to 100)
HI type b 1.0 mcg/mL threshold	58.4 (52.3 to 64.4)	54 (47.6 to 60.2)	100 (97.8 to 100)	97.9 (95.2 to 100)
Diphtheria toxoid at 0.01 IU/mL threshold	100 (98.7 to 100)	100 (98.6 to 100)	99.6 (98.6 to 100)	100 (98.6 to 100)
Diphtheria toxoid at 0.1 IU/mL threshold	89.7 (85.5 to 93)	94.2 (90.6 to 96.7)	100 (98.6 to 100)	100 (98.6 to 100)
Hepatitis B at $\geq 10.0$ mIU/mL	94.9 (91.7 to 97.2)	96.3 (93.2 to 98.2)	100 (97.4 to 99.9)	98.5 (96.1 to 99.9)

Notes:

[17] - N= Number of subjects with evaluable values.

[18] - N= Number of subjects with evaluable values.

[19] - N= Number of subjects with evaluable values.

[20] - N= Number of subjects with evaluable values.

## Statistical analyses

<b>Statistical analysis title</b>	HI Type b at 0.15 mcg/mL Threshold
Statistical analysis description: For Haemophilus influenzae type b the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.15 mcg/mL threshold was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[21]</sup>
Parameter estimate	Difference
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	8.3

Notes:

[21] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	HI Type b at 1.0 mcg/mL Threshold
Statistical analysis description: For Haemophilus influenzae (HI) type b the difference in percentages between the two groups (13vPnC - 7vPnC) at 1.0 mcg/mL threshold was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[22]</sup>
Parameter estimate	Difference
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	13

Notes:

[22] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	Diphtheria Toxoid (DT) at 0.01 IU/mL Threshold
Statistical analysis description: For diphtheria toxoid the difference in percentages between the two groups(13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[23]</sup>
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.5

Notes:

[23] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	DT at 0.1 IU/mL Threshold
Statistical analysis description: For DT the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.1 IU/mL threshold was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[24]</sup>
Parameter estimate	Difference
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	0.3

Notes:

[24] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	HI Type b at 0.15 mcg/mL Threshold
Statistical analysis description: For Haemophilus Influenzae Type b the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.15 mcg/mL threshold was calculated.	
Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	547
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[25]</sup>
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	1.5

Notes:

[25] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	Hepatitis B at $\geq 10.0$ mIU/mL Threshold
Statistical analysis description: For hepatitis B the difference in percentages between the two groups (13vPnC - 7vPnC) at $\geq 10.0$ mIU/mL threshold was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	564
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[26]</sup>
Parameter estimate	Difference
Point estimate	-1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	2.3

Notes:

[26] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	HI Type b at 1.0 mcg/mL Threshold
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Statistical analysis description:

For Haemophilus influenzae type b the difference in percentages between the two groups (13vPnC - 7vPnC) at 1.0 mcg/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	547
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[27]</sup>
Parameter estimate	Difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	4.4

Notes:

[27] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	DT at 0.01 IU/mL Threshold
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Statistical analysis description:

For diphtheria toxoid the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	547
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[28]</sup>
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Notes:

[28] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	DT at 0.1 IU/mL Threshold
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Statistical analysis description:

For diphtheria toxoid the difference in percentages between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
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Number of subjects included in analysis	547
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[29]</sup>
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Notes:

[29] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

<b>Statistical analysis title</b>	Hepatitis B at $\geq 10.0$ mIU/mL Threshold
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Statistical analysis description:

For hepatitis B the difference in percentages between the two groups (13vPnC - 7vPnC) at  $\geq 10.0$  mIU/mL threshold was calculated

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	547
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[30]</sup>
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	3.3

Notes:

[30] - Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.

**Primary: Geometric Mean Antibody Concentration of Haemophilus influenzae Type b in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose**

End point title	Geometric Mean Antibody Concentration of Haemophilus influenzae Type b in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose
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End point description:

Evaluable immunogenicity (per protocol) population of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after the infant series (5 months of age); one month after the toddler dose (13 months of age)

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	267 <sup>[31]</sup>	252 <sup>[32]</sup>	252 <sup>[33]</sup>	242 <sup>[34]</sup>
Units: mcg/ml				
geometric mean (confidence interval 95%)	1.23 (1.03 to 1.46)	1 (0.83 to 1.2)	11.79 (10.36 to 13.41)	10.24 (8.88 to 11.82)

Notes:

[31] - N=number of subjects with determinate antibody concentration for specified concomitant antigen

[32] - N=number of subjects with determinate antibody concentration for specified concomitant antigen

[33] - N=number of subjects with determinate antibody concentration for specified concomitant antigen

[34] - N=number of subjects with determinate antibody concentration for specified concomitant antigen

## Statistical analyses

Statistical analysis title	HI Type b GMC Ratio
Statistical analysis description:	
For Haemophilus influenzae type b the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	519
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[35]</sup>
Parameter estimate	Ratio
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.58

Notes:

[35] - Non-inferiority for the concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Statistical analysis title	HI Type b mcg/mL GMC Ratio
Statistical analysis description:	
For Haemophilus influenzae type b the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	7vPnC After Toddler Dose v 13vPnC After Toddler Dose
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[36]</sup>
Parameter estimate	Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.39

Notes:

[36] - Non-inferiority for the concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

## Primary: Geometric Mean Antibody Concentration of Diphtheria Toxoid in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration of Diphtheria Toxoid in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose
End point description:	Evaluable immunogenicity (per protocol) population of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (N)= number of subjects with a determinate antibody concentration for the specified concomitant antigen.
End point type	Primary
End point timeframe:	One month after the infant series (5 months of age); one month after the toddler dose (13 months of age)

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	272 <sup>[37]</sup>	258 <sup>[38]</sup>	269 <sup>[39]</sup>	260 <sup>[40]</sup>
Units: IU/mL				
geometric mean (confidence interval 95%)	0.36 (0.32 to 0.41)	0.53 (0.47 to 0.6)	2.67 (2.44 to 2.93)	3.08 (2.74 to 3.47)

Notes:

[37]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

[38]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

[39]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

[40]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

## Statistical analyses

<b>Statistical analysis title</b>	Diphtheria Toxoid IU/mL GMC Ratio
Statistical analysis description:	For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated.
Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[41]</sup>
Parameter estimate	Ratio
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.8

Notes:

[41] - Non-inferiority for the concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

<b>Statistical analysis title</b>	Diphtheria Toxoid IU/mL GMC Ratio
Statistical analysis description:	For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated.
Comparison groups	7vPnC After Toddler Dose v 13vPnC After Toddler Dose

Number of subjects included in analysis	529
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[42]</sup>
Parameter estimate	Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.01

Notes:

[42] - Non-inferiority for the concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

### Primary: Geometric Mean Antibody Concentration of Hepatitis B in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration of Hepatitis B in 13vPnC Group Relative to 7vPnC Group After the Infant Series and After the Toddler Dose
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End point description:

Antibody geometric mean concentration (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. Evaluable immunogenicity (per protocol) population of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary
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End point timeframe:

One month after the infant series (5 months of age); one month after the toddler dose (13 months of age)

End point values	13vPnC After the Infant Series	7vPnC After the Infant Series	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	277 <sup>[43]</sup>	268 <sup>[44]</sup>	271 <sup>[45]</sup>	259 <sup>[46]</sup>
Units: mIU/mL				
geometric mean (confidence interval 95%)	145.19 (122.62 to 171.92)	165.25 (140.33 to 194.61)	1118.05 (935.26 to 1336.56)	1195.82 (976.12 to 1464.98)

Notes:

[43]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

[44]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

[45]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

[46]

- N=number of subjects with determinate antibody concentration for specified concomitant antigen

### Statistical analyses

Statistical analysis title	Hepatitis B mIU/mL GMC Ratio
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Statistical analysis description:

For hepatitis B the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After the Infant Series v 7vPnC After the Infant Series
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Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[47]</sup>
Parameter estimate	Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.11

Notes:

[47] - Non-inferiority for the concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

<b>Statistical analysis title</b>	Hepatitis B mIU/mL GMC Ratio
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Statistical analysis description:

For hepatitis B the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC After Toddler Dose v 7vPnC After Toddler Dose
Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[48]</sup>
Parameter estimate	Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.22

Notes:

[48] - Non-inferiority for the concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMC ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

### **Primary: Geometric Mean Concentration in 13vPnC Group Relative to 7vPnC Group Before and After the Toddler Dose**

End point title	Geometric Mean Concentration in 13vPnC Group Relative to 7vPnC Group Before and After the Toddler Dose <sup>[49]</sup>
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End point description:

Antibody concentration/geometric mean concentration as measured by ELISA with their corresponding 95% CI immediately before and after the toddler dose for 7 common pneumococcal serotypes (Serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity (per protocol) population of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n)= number of subjects with a determinate antibody concentration for the specified concomitant antigen.

End point type	Primary
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End point timeframe:

Immediately before (12 months of age) and one month after the toddler dose (13 months of age)

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

<b>End point values</b>	13vPnC Before Toddler Dose	7vPnC Before Toddler Dose	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	279	268	279	268
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=277,264,276,263)	0.46 (0.42 to 0.51)	0.58 (0.53 to 0.64)	4.16 (3.75 to 4.62)	5.07 (4.53 to 5.67)
Common Serotypes - Serotype 6B (n=275,261,273,251)	0.97 (0.87 to 1.07)	1.06 (0.94 to 1.2)	9.14 (8.14 to 10.26)	9.85 (8.66 to 11.22)
Common Serotypes - Serotype 9V (n=277,265,277,262)	0.46 (0.42 to 0.5)	0.52 (0.48 to 0.57)	2.75 (2.52 to 2.99)	3.36 (3.02 to 3.73)
Common Serotypes - Serotype 14 (n=273,263,276,260)	2.2 (1.96 to 2.48)	2.65 (2.34 to 3)	8.34 (7.5 to 9.28)	11.01 (9.87 to 12.29)
Common Serotypes-Serotype 18C (n=277,265,276,263)	0.33 (0.3 to 0.36)	0.39 (0.36 to 0.43)	2.79 (2.53 to 3.07)	3.44 (3.08 to 3.84)
Common Serotypes-Serotype 19F (n=276,264,276,263)	0.68 (0.6 to 0.76)	0.58 (0.52 to 0.66)	5.99 (5.36 to 6.68)	4.72 (4.12 to 5.41)
Common Serotypes-Serotype 23F (n=275,264,277,264)	0.33 (0.3 to 0.37)	0.39 (0.34 to 0.45)	3.36 (2.98 to 3.78)	4.33 (3.75 to 5)
Additional - Serotype 1 (n=277,260,278,257)	0.52 (0.48 to 0.57)	0.03 (0.02 to 0.03)	4.25 (3.8 to 4.75)	0.03 (0.03 to 0.04)
Additional - Serotype 3 (n=275,261,278,255)	0.25 (0.23 to 0.28)	0.05 (0.05 to 0.06)	1.02 (0.92 to 1.13)	0.07 (0.06 to 0.08)
Additional - Serotype 5 (n=275,222,276,220)	0.74 (0.67 to 0.81)	0.34 (0.3 to 0.39)	3.56 (3.25 to 3.89)	0.51 (0.45 to 0.58)
Additional - Serotype 6A (n=276,259,274,255)	0.76 (0.68 to 0.85)	0.33 (0.29 to 0.37)	5.88 (5.24 to 6.59)	1.74 (1.51 to 2.01)
Additional - Serotype 7F (n=277,262,278,263)	0.99 (0.91 to 1.08)	0.04 (0.04 to 0.04)	4.79 (4.29 to 5.34)	0.05 (0.04 to 0.05)
Additional - Serotype 19A (n=277,259,271,260)	1.28 (1.14 to 1.45)	0.72 (0.65 to 0.8)	9.58 (8.68 to 10.58)	3.79 (3.4 to 4.21)

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions

End point title	Percentage of Subjects Reporting Pre-Specified Local
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End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (Sig) (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (Mod)(2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population, included subjects who received given dose; (n) = number of subjects reporting the specific characteristic.

End point type	Primary
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End point timeframe:

Day 1 through 4 after each dose

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

<b>End point values</b>	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	300	303	296	297
Units: Percentage of subjects				
number (not applicable)				
Tenderness-Any (n=267,267,250,241,229,221,206,96)	33	32.6	29.2	31.5
Tenderness-Sig (n=260,258,236,226,215,209,176,158)	7.7	7	4.7	7.5
Swelling-Any (n=266,263,244,242,226,224,190,176)	28.2	20.5	26.6	35.1
Swelling-Mild (n=265,263,243,239,226,223,186,172)	24.5	19	24.3	33.5
Swelling-Mod (n=261,256,235,227,217,211,174,158)	7.3	5.9	7.7	6.6
Swelling- Severe(n=259,255,232,223,214,208,16	0	0	0	0
Redness-Any (n=266,272,247,252,238,231,196,184)	28.2	36.4	34.4	46.8
Redness-Mild (n=265,271,247,250,237,229,191,180)	27.2	36.2	33.6	45.6
Redness-Mod (n=260,256,232,224,217,210,173,158)	1.9	1.6	1.7	3.6
Redness-Severe (n=259,255,232,222,214,208,166,153)	0	0	0	0

<b>End point values</b>	13vPnC Dose 3	7vPnC Dose 3	13vPnC Toddler dose	7vPnC Toddler dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	294	293	290	287
Units: Percentage of subjects				
number (not applicable)				
Tenderness-Any (n=267,267,250,241,229,221,206,96)	27.1	21.3	53.4	51.9
Tenderness-Sig (n=260,258,236,226,215,209,176,158)	4.2	2.9	10.8	12.7
Swelling-Any (n=266,263,244,242,226,224,190,176)	26.1	28.6	36.8	43.8
Swelling-Mild (n=265,263,243,239,226,223,186,172)	24.8	27.8	33.3	40.7
Swelling-Mod (n=261,256,235,227,217,211,174,158)	6.9	5.2	12.1	12.7
Swelling- Severe(n=259,255,232,223,214,208,16	0	0	0	0
Redness-Any (n=266,272,247,252,238,231,196,184)	34.9	39.8	47.4	56
Redness-Mild (n=265,271,247,250,237,229,191,180)	34.2	38.9	44.5	52.8
Redness-Mod (n=260,256,232,224,217,210,173,158)	4.6	2.4	11.6	15.2
Redness-Severe (n=259,255,232,222,214,208,166,153)	0	0	0	0.7

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of subjects Reporting Pre-Specified Systemic Events (Infant Series)

End point title	Percentage of subjects Reporting Pre-Specified Systemic Events (Infant Series) <sup>[51]</sup>
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End point description:

Systemic events (any fever  $\geq 38$  degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, hives [urticaria], were reported using an electronic diary. subjects may be represented in more than 1 category. Safety population, subjects who received given dose; (n)= number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary
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End point timeframe:

Day 1 through 4 after each dose

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	300	303	296	297
Units: Percentage of Subjects				
number (not applicable)				
Fever $\geq 38^{\circ}\text{C}$ but ( $\leq$ ) $\leq 39^{\circ}\text{C}$ (n=269,266,248,250,242,232)	43.5	38.7	46.8	48.4
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ (n=260,256,238,225,216,210)	4.2	1.6	8.8	4.4
Fever $> 40^{\circ}\text{C}$ (n=259,256,233,223,216,209)	0	0	0	0
Decreased Appetite (n=269,267,249,245,236,225)	33.1	30.3	33.7	34.3
Irritability (n=275,266,254,252,238,235)	42.5	45.1	47.2	55.2
Increased Sleep (n=284,272,258,256,240,241)	61.6	58.8	53.9	66.8
Decreased Sleep (n=266,264,240,234,230,221)	25.2	26.1	23.8	23.1
Meds to Prevent Sx (n=261,262,237,234,220,220)	8.8	9.5	10.1	15.4
Meds to Treat Sx (n=263,266,244,235,226,225)	20.2	21.1	28.3	27.2

End point values	13vPnC Dose 3	7vPnC Dose 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	294	293		
Units: Percentage of Subjects				
number (not applicable)				
Fever $\geq 38^{\circ}\text{C}$ but ( $\leq$ ) $\leq 39^{\circ}\text{C}$ (n=269,266,248,250,242,232)	46.3	36.6		
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ (n=260,256,238,225,216,210)	3.7	1.4		

Fever >40°C (n=259,256,233,223,216,209)	0	0		
Decreased Appetite (n=269,267,249,245,236,225)	33.1	30.2		
Irritability (n=275,266,254,252,238,235)	45.4	48.9		
Increased Sleep (n=284,272,258,256,240,241)	49.6	49.4		
Decreased Sleep (n=266,264,240,234,230,221)	20.9	24.4		
Meds to Prevent Sx (n=261,262,237,234,220,220)	10	15		
Meds to Treat Sx (n=263,266,244,235,226,225)	20.8	19.1		

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events (Toddler Series)

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events (Toddler Series) <sup>[52]</sup>
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End point description:

Systemic events (any fever  $\geq$  38 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, subjects who received given dose; (n)= number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary
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End point timeframe:

Day 1 through 4 after each dose

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	290	287		
Units: Percentage of Subjects				
number (not applicable)				
Fever $\geq$ 38°C but $\leq$ 39°C (n=206,200)	58.7	62		
Fever >39°C but $\leq$ 40°C (n=174,157)	12.6	8.9		
Fever >40°C (n=166,152)	0.6	0		
Decreased Appetite (n=204,192)	43.6	46.4		
Irritability (n=213,200)	55.4	61		
Increased Sleep (n=202,197)	56.4	54.8		
Decreased Sleep (n=195,170)	31.8	28.8		
Medication to Prevent Symptoms (n=184,182)	32.1	33		

Medication to Treat Symptoms (n=178,167)	18	18.6		
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### **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

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### Adverse events information

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Timeframe for reporting adverse events:

AEs were recorded from the signing of the ICF to visit 4 and from visit 5 to visit 6. SAEs were recorded from the signing of the ICF to 6 months after the final study vaccination.

Adverse event reporting additional description:

Version was not captured, hence 0.0 is mentioned for dictionary version. Local reactions (LRs) and systemic events (SEs) were to be assessed only for infant series and toddler dose groups.

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Assessment type	Non-systematic
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### Dictionary used

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Dictionary name	MedDRA
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Dictionary version	0.0
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### Reporting groups

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Reporting group title	13vPnC Infant Series
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Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 2, 3, 4 months. Adverse events were collected from dose 1 to approximately one month after dose 3.

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Reporting group title	7vPnC Infant Series
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Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 2, 3, 4 months. Adverse events were collected from dose 1 to approximately one month after dose 3.

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Reporting group title	13vPnC Post-Infant Series
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Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 2, 3, 4 months. Adverse events were collected from approximately one month after dose 3 to toddler dose.

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Reporting group title	7vPnC Post-Infant Series
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Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 2, 3, 4 months (infant series). Adverse events were collected from approximately one month after dose 3 to toddler dose.

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Reporting group title	13vPnC Toddler Dose
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Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC at 12 months of age. Adverse events were collected for approximately one month after toddler dose

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Reporting group title	7vPnC Toddler Dose
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Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 12 months of age. Adverse events were collected for approximately one month after toddler dose.

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Reporting group title	13vPnC 6-Month Follow-up
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Reporting group description:

Subjects received one single 0.5mL dose of 13vPnC coadministered with Infanrix hexa at 2, 3, 4 months (infant series) and 12 months of age (toddler dose). Adverse events were collected for approximately six months after last study vaccine.

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Reporting group title	7vPnC 6-Month Follow-up
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Reporting group description:

Subjects received one single 0.5mL dose of 7vPnC coadministered with Infanrix hexa at 2, 3, 4 months (infant series) and 12 months of age (toddler dose). Adverse events were collected for approximately six months after last study vaccine.

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<b>Serious adverse events</b>	13vPnC Infant Series	7vPnC Infant Series	13vPnC Post-Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 299 (4.01%)	10 / 300 (3.33%)	16 / 299 (5.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
<b>Injury, poisoning and procedural complications</b>			
Brain contusion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
Laceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
Concussion			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skeletal injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	2 / 299 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical poisoning			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Head injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
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			
Vitello-intestinal duct remnant			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ileus paralytic			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
Mechanical ileus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (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
<b>Reproductive system and breast disorders</b>			
Epididymitis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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
<b>Respiratory, thoracic and mediastinal disorders</b>			
Respiratory failure			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoeic attack			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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
<b>Musculoskeletal and connective tissue disorders</b>			
Muscle twitching			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Gastroenteritis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	2 / 299 (0.67%)	2 / 300 (0.67%)	2 / 299 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			

subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
<b>Bronchitis</b>			
subjects affected / exposed	2 / 299 (0.67%)	4 / 300 (1.33%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Upper respiratory tract infection</b>			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (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
<b>Pneumonia</b>			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyelonephritis</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
<b>Bronchopneumonia</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Croup infectious</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
<b>Cystitis</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Otitis media</b>			

subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 299 (0.00%)	2 / 300 (0.67%)	0 / 299 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (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
Bronchiolitis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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
Febrile infection			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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
Viral tonsillitis			

subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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
<b>Gastroenteritis norovirus</b>			
subjects affected / exposed <sup>[1]</sup>	0 / 299 (0.00%)	0 / 299 (0.00%)	0 / 299 (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
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
<b>Feeding disorder neonatal</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
<b>Metabolic acidosis</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (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
<b>Acidosis</b>			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Failure to thrive</b>			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Decreased appetite</b>			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (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

<b>Serious adverse events</b>	7vPnC Post-Infant	13vPnC Toddler	7vPnC Toddler Dose
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	Series	Dose	
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 300 (5.00%)	3 / 289 (1.04%)	4 / 284 (1.41%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
Laceration			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
Concussion			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (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
Skeletal injury			
subjects affected / exposed	3 / 300 (1.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical poisoning			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
Accidental exposure			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
Contusion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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

Head injury			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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			
Vitello-intestinal duct remnant			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
Gastrointestinal disorders			
Ileus paralytic			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
Intussusception			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
Mechanical ileus			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Reproductive system and breast disorders</b>			
Epididymitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Respiratory, thoracic and mediastinal disorders</b>			
Respiratory failure			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
Apnoeic attack			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Musculoskeletal and connective tissue disorders</b>			
Muscle twitching			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Infections and infestations</b>			
Gastroenteritis			
subjects affected / exposed	4 / 300 (1.33%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	3 / 300 (1.00%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Bronchitis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Upper respiratory tract infection</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonia</b>			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
<b>Pyelonephritis</b>			
subjects affected / exposed	2 / 300 (0.67%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchopneumonia</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Croup infectious</b>			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
<b>Cystitis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Otitis media</b>			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
Bronchiolitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral tonsillitis			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Gastroenteritis norovirus</b>			
subjects affected / exposed <sup>[1]</sup>	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (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
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	1 / 300 (0.33%)	1 / 289 (0.35%)	0 / 284 (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
<b>Feeding disorder neonatal</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Metabolic acidosis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Acidosis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Failure to thrive</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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
<b>Decreased appetite</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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

<b>Serious adverse events</b>	13vPnC 6-Month	7vPnC 6-Month	
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	Follow-up	Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 287 (3.83%)	14 / 287 (4.88%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skeletal injury			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical poisoning			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental exposure			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Head injury			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Vitello-intestinal duct remnant			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 287 (0.00%)	1 / 287 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ileus paralytic			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			

subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
Epididymitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
Respiratory failure			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apnoeic attack			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
Muscle twitching			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
Gastroenteritis			
subjects affected / exposed	3 / 287 (1.05%)	3 / 287 (1.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 287 (0.35%)	3 / 287 (1.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			

subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			

subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral tonsillitis			

subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
subjects affected / exposed <sup>[1]</sup>	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 287 (0.70%)	1 / 287 (0.35%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeding disorder neonatal			
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acidosis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

<b>Non-serious adverse events</b>	13vPnC Infant Series	7vPnC Infant Series	13vPnC Post-Infant Series
Total subjects affected by non-serious adverse events subjects affected / exposed	256 / 299 (85.62%)	253 / 300 (84.33%)	13 / 299 (4.35%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Haemangioma subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Melanocytic naevus subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	29 / 299 (9.70%) 34	27 / 300 (9.00%) 31	0 / 299 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	2 / 299 (0.67%) 2	2 / 300 (0.67%) 2	0 / 299 (0.00%) 0
Injection site swelling subjects affected / exposed occurrences (all)	3 / 299 (1.00%) 4	4 / 300 (1.33%) 5	0 / 299 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	1 / 300 (0.33%) 2	0 / 299 (0.00%) 0
Injection site induration subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	3 / 300 (1.00%) 5	0 / 299 (0.00%) 0
Irritability subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Developmental delay			

subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	1 / 299 (0.33%) 2
Granuloma subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Injection site haematoma subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Injection site reaction subjects affected / exposed occurrences (all)	2 / 299 (0.67%) 2	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 2	0 / 299 (0.00%) 0
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[2]</sup> occurrences (all)	117 / 269 (43.49%) 117	103 / 266 (38.72%) 103	0 / 299 (0.00%) 0
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[3]</sup> occurrences (all)	11 / 260 (4.23%) 11	4 / 256 (1.56%) 4	0 / 299 (0.00%) 0
Fever $> 40^{\circ}\text{C}$ Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[4]</sup> occurrences (all)	0 / 259 (0.00%) 0	0 / 256 (0.00%) 0	0 / 299 (0.00%) 0
Decreased appetite Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed <sup>[5]</sup> occurrences (all)	89 / 269 (33.09%) 89	81 / 267 (30.34%) 81	0 / 299 (0.00%) 0
Irritability Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[6]</sup> occurrences (all)	117 / 275 (42.55%) 117	120 / 266 (45.11%) 120	0 / 299 (0.00%) 0
Increased sleep Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[7]</sup> occurrences (all)	175 / 284 (61.62%) 175	160 / 272 (58.82%) 160	0 / 299 (0.00%) 0
Decreased sleep Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[8]</sup> occurrences (all)	67 / 266 (25.19%) 67	69 / 264 (26.14%) 69	0 / 299 (0.00%) 0
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[9]</sup> occurrences (all)	116 / 248 (46.77%) 116	121 / 250 (48.40%) 121	0 / 299 (0.00%) 0
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[10]</sup> occurrences (all)	21 / 238 (8.82%) 21	10 / 225 (4.44%) 10	0 / 299 (0.00%) 0
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed <sup>[11]</sup> occurrences (all)	84 / 249 (33.73%) 84	84 / 245 (34.29%) 84	0 / 299 (0.00%) 0
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[12]</sup> occurrences (all)	120 / 254 (47.24%) 120	139 / 252 (55.16%) 139	0 / 299 (0.00%) 0
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[13]</sup> occurrences (all)	139 / 258 (53.88%) 139	171 / 256 (66.80%) 171	0 / 299 (0.00%) 0
Decreased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[14]</sup> occurrences (all)	57 / 240 (23.75%) 57	54 / 234 (23.08%) 54	0 / 299 (0.00%) 0
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[15]</sup> occurrences (all)	112 / 242 (46.28%) 112	85 / 232 (36.64%) 85	0 / 299 (0.00%) 0
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[16]</sup> occurrences (all)	8 / 216 (3.70%) 8	3 / 210 (1.43%) 3	0 / 299 (0.00%) 0
Fever $> 40^{\circ}\text{C}$ Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic subjects affected / exposed <sup>[17]</sup> occurrences (all)	2 / 216 (0.93%) 2	0 / 209 (0.00%) 0	0 / 299 (0.00%) 0
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[18]</sup> occurrences (all)	78 / 236 (33.05%) 78	68 / 225 (30.22%) 68	0 / 299 (0.00%) 0
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[19]</sup> occurrences (all)	108 / 238 (45.38%) 108	115 / 235 (48.94%) 115	0 / 299 (0.00%) 0
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[20]</sup> occurrences (all)	119 / 240 (49.58%) 119	119 / 241 (49.38%) 119	0 / 299 (0.00%) 0
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[21]</sup> occurrences (all)	48 / 230 (20.87%) 48	54 / 221 (24.43%) 54	0 / 299 (0.00%) 0
Immune system disorders			
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Atopy			

subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Reproductive system and breast disorders			
Balanitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Vulval disorder subjects affected / exposed occurrences (all)	5 / 299 (1.67%) 5	7 / 300 (2.33%) 7	0 / 299 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Asthma subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Bronchial hyperreactivity subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Tonsillar disorder subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	12 / 299 (4.01%) 15	7 / 300 (2.33%) 9	0 / 299 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Bronchial obstruction			

subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Obstructive airways disorder subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Pharyngolaryngeal pain subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Stridor subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Supraclavicular retraction subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Wheezing subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Sleep disorder subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	1 / 299 (0.33%) 1
Screaming subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Agitation subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Crying subjects affected / exposed occurrences (all)	11 / 299 (3.68%) 13	10 / 300 (3.33%) 13	0 / 299 (0.00%) 0
Restlessness subjects affected / exposed occurrences (all)	7 / 299 (2.34%) 9	14 / 300 (4.67%) 15	0 / 299 (0.00%) 0

Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Blood immunoglobulin e increased			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	3 / 299 (1.00%)	2 / 300 (0.67%)	0 / 299 (0.00%)
occurrences (all)	3	2	0
Laceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	1 / 299 (0.33%)	2 / 300 (0.67%)	1 / 299 (0.33%)
occurrences (all)	1	2	1
Accidental exposure			

subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Skeletal injury subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	21 / 299 (7.02%) 25	22 / 300 (7.33%) 23	0 / 299 (0.00%) 0
Clavicle fracture subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Exposure to toxic agent subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Nicotine poisoning subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Brain contusion subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Congenital, familial and genetic disorders			
21-hydroxylase deficiency subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Cryptorchism subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Dacryostenosis congenital subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	2 / 300 (0.67%) 2	0 / 299 (0.00%) 0
Congenital torticollis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
CranioTabes			

subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Hereditary fructose intolerance subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Macrocephaly subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Naevus flammeus subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Pectus excavatum subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Plagiocephaly subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
<b>Nervous system disorders</b>			
Hypokinesia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	2 / 300 (0.67%) 2	0 / 299 (0.00%) 0
Pseudoparalysis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Hypersomnia subjects affected / exposed occurrences (all)	3 / 299 (1.00%) 3	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
High-pitched crying subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Fine motor delay subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Coordination abnormal subjects affected / exposed occurrences (all)	3 / 299 (1.00%) 3	7 / 300 (2.33%) 7	0 / 299 (0.00%) 0

Hypotonia			
subjects affected / exposed	1 / 299 (0.33%)	3 / 300 (1.00%)	0 / 299 (0.00%)
occurrences (all)	1	3	0
Hypertonia			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Myotonia			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Poor quality sleep			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Febrile convulsion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
<b>Blood and lymphatic system disorders</b>			
Iron deficiency anaemia			
subjects affected / exposed	2 / 299 (0.67%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	2	1	0
Anaemia			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Mastocytosis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences (all)	0	0	1
<b>Ear and labyrinth disorders</b>			
Middle ear effusion			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Middle ear disorder			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Ear pain			

subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Otosalpingitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Eye disorders			
Hypermetropia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Strabismus subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	22 / 299 (7.36%) 23	25 / 300 (8.33%) 30	0 / 299 (0.00%) 0
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Eyelid disorder subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Dacryostenosis acquired subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	2 / 300 (0.67%) 2	0 / 299 (0.00%) 0
Pupils unequal subjects affected / exposed occurrences (all)	2 / 299 (0.67%) 2	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Dacryoadenitis acquired subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Eye inflammation subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	21 / 299 (7.02%)	14 / 300 (4.67%)	0 / 299 (0.00%)
occurrences (all)	23	15	0
Teething			
subjects affected / exposed	6 / 299 (2.01%)	8 / 300 (2.67%)	0 / 299 (0.00%)
occurrences (all)	7	9	0
Vomiting			
subjects affected / exposed	8 / 299 (2.68%)	7 / 300 (2.33%)	0 / 299 (0.00%)
occurrences (all)	8	7	0
Constipation			
subjects affected / exposed	11 / 299 (3.68%)	6 / 300 (2.00%)	0 / 299 (0.00%)
occurrences (all)	12	6	0
Flatulence			
subjects affected / exposed	11 / 299 (3.68%)	8 / 300 (2.67%)	0 / 299 (0.00%)
occurrences (all)	13	10	0
Abdominal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Dental discomfort			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	5 / 299 (1.67%)	2 / 300 (0.67%)	0 / 299 (0.00%)
occurrences (all)	5	2	0
Stomatitis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Infantile colic			

subjects affected / exposed occurrences (all)	2 / 299 (0.67%) 3	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Anal prolapse subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Gastroesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
<b>Skin and subcutaneous tissue disorders</b>			
Neurodermatitis subjects affected / exposed occurrences (all)	3 / 299 (1.00%) 3	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	22 / 299 (7.36%) 24	25 / 300 (8.33%) 29	0 / 299 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	10 / 299 (3.34%) 10	14 / 300 (4.67%) 15	2 / 299 (0.67%) 2
Eczema infantile subjects affected / exposed occurrences (all)	6 / 299 (2.01%) 6	6 / 300 (2.00%) 6	1 / 299 (0.33%) 1
Rash subjects affected / exposed occurrences (all)	4 / 299 (1.34%) 5	5 / 300 (1.67%) 5	0 / 299 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	3 / 300 (1.00%) 3	0 / 299 (0.00%) 0
Seborrhoeic dermatitis subjects affected / exposed occurrences (all)	7 / 299 (2.34%) 7	5 / 300 (1.67%) 5	0 / 299 (0.00%) 0
Eczema asteatotic subjects affected / exposed occurrences (all)	3 / 299 (1.00%) 3	4 / 300 (1.33%) 4	0 / 299 (0.00%) 0
Dermatitis allergic subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0

Dry skin			
subjects affected / exposed	2 / 299 (0.67%)	3 / 300 (1.00%)	0 / 299 (0.00%)
occurrences (all)	2	3	0
Intertrigo			
subjects affected / exposed	1 / 299 (0.33%)	5 / 300 (1.67%)	0 / 299 (0.00%)
occurrences (all)	1	5	0
Rash generalised			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 299 (0.00%)	2 / 300 (0.67%)	0 / 299 (0.00%)
occurrences (all)	0	2	0
Dermatitis atopic			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Hirsutism			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Rash neonatal			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0

Skin exfoliation			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Skin induration			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Vitiligo			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Tenderness (Any) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[22]</sup>	88 / 267 (32.96%)	87 / 267 (32.58%)	0 / 299 (0.00%)
occurrences (all)	88	87	0
Tenderness (Significant) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[23]</sup>	20 / 260 (7.69%)	18 / 258 (6.98%)	0 / 299 (0.00%)
occurrences (all)	20	18	0
Induration (Any) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[24]</sup>	75 / 266 (28.20%)	54 / 263 (20.53%)	0 / 299 (0.00%)
occurrences (all)	75	54	0
Induration (Mild) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[25]</sup>	65 / 265 (24.53%)	50 / 263 (19.01%)	0 / 299 (0.00%)
occurrences (all)	65	50	0

Induration (Moderate) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[26]</sup> occurrences (all)	19 / 261 (7.28%) 19	15 / 256 (5.86%) 15	0 / 299 (0.00%) 0
Erythema (Any) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[27]</sup> occurrences (all)	75 / 266 (28.20%) 75	99 / 272 (36.40%) 99	0 / 299 (0.00%) 0
Erythema (Mild) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[28]</sup> occurrences (all)	72 / 265 (27.17%) 72	98 / 271 (36.16%) 98	0 / 299 (0.00%) 0
Erythema (Moderate) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[29]</sup> occurrences (all)	5 / 260 (1.92%) 5	4 / 256 (1.56%) 4	0 / 299 (0.00%) 0
Erythema (Severe) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[30]</sup> occurrences (all)	0 / 259 (0.00%) 0	0 / 255 (0.00%) 0	0 / 299 (0.00%) 0
Tenderness (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[31]</sup> occurrences (all)	73 / 250 (29.20%) 73	76 / 241 (31.54%) 76	0 / 299 (0.00%) 0

Tenderness (Significant) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[32]</sup> occurrences (all)	11 / 236 (4.66%) 11	17 / 226 (7.52%) 17	0 / 299 (0.00%) 0
Induration (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[33]</sup> occurrences (all)	65 / 244 (26.64%) 65	85 / 242 (35.12%) 85	0 / 299 (0.00%) 0
Induration (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[34]</sup> occurrences (all)	59 / 243 (24.28%) 59	80 / 239 (33.47%) 80	0 / 299 (0.00%) 0
Induration (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[35]</sup> occurrences (all)	18 / 235 (7.66%) 18	15 / 227 (6.61%) 15	0 / 299 (0.00%) 0
Erythema (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[36]</sup> occurrences (all)	85 / 247 (34.41%) 85	118 / 252 (46.83%) 118	0 / 299 (0.00%) 0
Erythema (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[37]</sup> occurrences (all)	83 / 247 (33.60%) 83	114 / 250 (45.60%) 114	0 / 299 (0.00%) 0

Erythema (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: lo 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[38]</sup> occurrences (all)	4 / 232 (1.72%) 4	8 / 224 (3.57%) 8	0 / 299 (0.00%) 0
Tenderness (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[39]</sup> occurrences (all)	62 / 229 (27.07%) 62	47 / 221 (21.27%) 47	0 / 299 (0.00%) 0
Tenderness (Significant) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[40]</sup> occurrences (all)	9 / 215 (4.19%) 9	6 / 209 (2.87%) 6	0 / 299 (0.00%) 0
Induration (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[41]</sup> occurrences (all)	59 / 226 (26.11%) 59	64 / 224 (28.57%) 64	0 / 299 (0.00%) 0
Induration (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[42]</sup> occurrences (all)	56 / 226 (24.78%) 56	62 / 223 (27.80%) 62	0 / 299 (0.00%) 0
Induration (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[43]</sup> occurrences (all)	15 / 217 (6.91%) 15	11 / 211 (5.21%) 11	0 / 299 (0.00%) 0

Erythema (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[44]</sup> occurrences (all)	83 / 238 (34.87%) 83	92 / 231 (39.83%) 92	0 / 299 (0.00%) 0
Erythema (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[45]</sup> occurrences (all)	81 / 237 (34.18%) 81	89 / 229 (38.86%) 89	0 / 299 (0.00%) 0
Erythema (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[46]</sup> occurrences (all)	10 / 217 (4.61%) 10	5 / 210 (2.38%) 5	0 / 299 (0.00%) 0
Renal and urinary disorders			
Urinary tract disorder subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Ureteric stenosis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Vesicoureteric reflux subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Pain in extremity subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Joint range of motion decreased subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Foot deformity			

subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Posture abnormal subjects affected / exposed occurrences (all)	2 / 299 (0.67%) 2	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Arthropathy subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Exostosis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Head deformity subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Hypotonia neonatal subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	75 / 299 (25.08%) 95	64 / 300 (21.33%) 83	2 / 299 (0.67%) 2
Bronchitis subjects affected / exposed occurrences (all)	49 / 299 (16.39%) 52	45 / 300 (15.00%) 55	2 / 299 (0.67%) 3
Rhinitis subjects affected / exposed occurrences (all)	24 / 299 (8.03%) 29	32 / 300 (10.67%) 37	2 / 299 (0.67%) 2
Nasopharyngitis subjects affected / exposed occurrences (all)	19 / 299 (6.35%) 23	28 / 300 (9.33%) 33	0 / 299 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	7 / 299 (2.34%) 7	13 / 300 (4.33%) 14	0 / 299 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	11 / 299 (3.68%) 11	14 / 300 (4.67%) 14	0 / 299 (0.00%) 0

Febrile infection			
subjects affected / exposed	7 / 299 (2.34%)	10 / 300 (3.33%)	0 / 299 (0.00%)
occurrences (all)	8	10	0
Croup infectious			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Exanthema subitum			
subjects affected / exposed	4 / 299 (1.34%)	4 / 300 (1.33%)	0 / 299 (0.00%)
occurrences (all)	4	4	0
Oral candidiasis			
subjects affected / exposed	9 / 299 (3.01%)	12 / 300 (4.00%)	0 / 299 (0.00%)
occurrences (all)	9	12	0
Pharyngitis			
subjects affected / exposed	2 / 299 (0.67%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	2	1	0
Candida nappy rash			
subjects affected / exposed	4 / 299 (1.34%)	5 / 300 (1.67%)	0 / 299 (0.00%)
occurrences (all)	4	5	0
Tonsillitis			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Acute tonsillitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	3 / 299 (1.00%)	5 / 300 (1.67%)	0 / 299 (0.00%)
occurrences (all)	4	5	0
Influenza			
subjects affected / exposed	2 / 299 (0.67%)	4 / 300 (1.33%)	0 / 299 (0.00%)
occurrences (all)	2	4	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Bronchitis viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0

Bronchopneumonia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	2 / 299 (0.67%)	3 / 300 (1.00%)	0 / 299 (0.00%)
occurrences (all)	2	3	0
Fungal infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Omphalitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Otitis externa			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0

Otitis media acute			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Pseudocroup			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	6 / 299 (2.01%)	3 / 300 (1.00%)	0 / 299 (0.00%)
occurrences (all)	6	3	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 299 (0.00%)	2 / 300 (0.67%)	0 / 299 (0.00%)
occurrences (all)	0	2	0
Rhinolaryngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Tinea infection			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Tracheitis			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Tracheobronchitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0

Viral skin infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 300 (0.00%)	1 / 299 (0.33%)
occurrences (all)	0	0	1
Varicella			
subjects affected / exposed	3 / 299 (1.00%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	3	0	0
Ear infection			
subjects affected / exposed	3 / 299 (1.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	3	1	0
Bacterial infection			
subjects affected / exposed	2 / 299 (0.67%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Bronchiolitis			
subjects affected / exposed	2 / 299 (0.67%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Genital candidiasis			
subjects affected / exposed	1 / 299 (0.33%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Viral rash			
subjects affected / exposed	2 / 299 (0.67%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	3	0	0
Abscess			
subjects affected / exposed	1 / 299 (0.33%)	0 / 300 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Bacterial rhinitis			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Bronchitis bacterial			
subjects affected / exposed	0 / 299 (0.00%)	1 / 300 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0

Conjunctivitis infective subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Eczema infected subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Gastrointestinal infection subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Otitis media viral subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Pertussis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Postoperative wound infection subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Sinobronchitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Tonsillitis streptococcal subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Viral diarrhoea subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Viral rhinitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0

Burns second degree subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Skin candida subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	3 / 300 (1.00%) 4	0 / 299 (0.00%) 0
Periorbital cellulitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Pharyngotonsillitis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Gastroenteritis rotavirus subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Metabolism and nutrition disorders			
Feeding disorder neonatal subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Hyperphosphatasaemia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Weight gain poor subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 2	2 / 300 (0.67%) 2	0 / 299 (0.00%) 0
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Acidosis			

subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Failure to thrive subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Obesity subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 300 (0.33%) 1	0 / 299 (0.00%) 0
Oral intake reduced subjects affected / exposed occurrences (all)	1 / 299 (0.33%) 1	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0
Metabolic acidosis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 300 (0.00%) 0	0 / 299 (0.00%) 0

<b>Non-serious adverse events</b>	7vPnC Post-Infant Series	13vPnC Toddler Dose	7vPnC Toddler Dose
Total subjects affected by non-serious adverse events subjects affected / exposed	25 / 300 (8.33%)	217 / 289 (75.09%)	208 / 284 (73.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Haemangioma subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Melanocytic naevus subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	14 / 289 (4.84%) 14	28 / 284 (9.86%) 29
Injection site erythema subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	4 / 289 (1.38%) 4	5 / 284 (1.76%) 5
Injection site swelling subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	3 / 289 (1.04%) 3	5 / 284 (1.76%) 5
Injection site pain			

subjects affected / exposed	0 / 300 (0.00%)	2 / 289 (0.69%)	4 / 284 (1.41%)
occurrences (all)	0	2	4
Injection site induration			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	4 / 284 (1.41%)
occurrences (all)	0	1	4
Irritability			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	1 / 284 (0.35%)
occurrences (all)	0	3	1
Developmental delay			
subjects affected / exposed	1 / 300 (0.33%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	1	1	0
Granuloma			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Injection site haematoma			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ Dose 1 and Toddler dose			
Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.			
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[2]</sup>	0 / 300 (0.00%)	121 / 206 (58.74%)	124 / 200 (62.00%)
occurrences (all)	0	121	124
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ Dose 1 and Toddler dose			
Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.			
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[3]</sup>	0 / 300 (0.00%)	22 / 174 (12.64%)	14 / 157 (8.92%)
occurrences (all)	0	22	14
Fever $> 40^{\circ}\text{C}$ Dose 1 and Toddler			
Additional description: Dose 1: Subjects affected and occurrences for SE is same			

dose	as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[4]</sup>	0 / 300 (0.00%)	1 / 166 (0.60%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Decreased appetite Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[5]</sup>	0 / 300 (0.00%)	89 / 204 (43.63%)	89 / 192 (46.35%)
occurrences (all)	0	89	89
Irritability Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[6]</sup>	0 / 300 (0.00%)	118 / 213 (55.40%)	122 / 200 (61.00%)
occurrences (all)	0	118	122
Increased sleep Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[7]</sup>	0 / 300 (0.00%)	114 / 202 (56.44%)	108 / 197 (54.82%)
occurrences (all)	0	114	108
Decreased sleep Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[8]</sup>	0 / 300 (0.00%)	62 / 195 (31.79%)	49 / 170 (28.82%)
occurrences (all)	0	62	49
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[9]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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		

<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[10]</sup></p> <p>occurrences (all)</p>	<p>as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
	<p>0 / 300 (0.00%)</p> <p>0</p>	<p>0 / 289 (0.00%)</p> <p>0</p>	<p>0 / 284 (0.00%)</p> <p>0</p>
<p>Decreased appetite Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[11]</sup></p> <p>occurrences (all)</p>	<p>0 / 300 (0.00%)</p> <p>0</p>	<p>0 / 289 (0.00%)</p> <p>0</p>	<p>0 / 284 (0.00%)</p> <p>0</p>
<p>Irritability Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[12]</sup></p> <p>occurrences (all)</p>	<p>0 / 300 (0.00%)</p> <p>0</p>	<p>0 / 289 (0.00%)</p> <p>0</p>	<p>0 / 284 (0.00%)</p> <p>0</p>
<p>Increased sleep Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[13]</sup></p> <p>occurrences (all)</p>	<p>0 / 300 (0.00%)</p> <p>0</p>	<p>0 / 289 (0.00%)</p> <p>0</p>	<p>0 / 284 (0.00%)</p> <p>0</p>
<p>Decreased sleep Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[14]</sup></p> <p>occurrences (all)</p>	<p>0 / 300 (0.00%)</p> <p>0</p>	<p>0 / 289 (0.00%)</p> <p>0</p>	<p>0 / 284 (0.00%)</p> <p>0</p>
<p>Fever <math>\geq 38^{\circ}\text{C}</math> but <math>\leq 39^{\circ}\text{C}</math> Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p>			

subjects affected / exposed <sup>[15]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[16]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Fever >40°C Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[17]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Decreased appetite Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[18]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Irritability Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[19]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Increased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[20]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Decreased sleep Dose 3	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type:			

Systematic subjects affected / exposed <sup>[21]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Immune system disorders			
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Atopy subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Reproductive system and breast disorders			
Balinitis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	1 / 284 (0.35%) 1
Vulval disorder subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	1 / 284 (0.35%) 1
Respiratory, thoracic and mediastinal disorders			
Asthma subjects affected / exposed occurrences (all)	2 / 300 (0.67%) 2	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Bronchial hyperreactivity subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Tonsillar disorder subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Cough			

subjects affected / exposed	0 / 300 (0.00%)	7 / 289 (2.42%)	3 / 284 (1.06%)
occurrences (all)	0	7	3
<b>Dysphonia</b>			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
<b>Dyspnoea</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
<b>Epistaxis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
<b>Bronchial obstruction</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Obstructive airways disorder</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Pharyngolaryngeal pain</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Stridor</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Supraclavicular retraction</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Wheezing</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Psychiatric disorders</b>			
<b>Insomnia</b>			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	3 / 284 (1.06%)
occurrences (all)	0	3	3
<b>Sleep disorder</b>			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	0 / 284 (0.00%)
occurrences (all)	0	3	0

Screaming subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Agitation subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Crying subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	2 / 284 (0.70%) 2
Restlessness subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	3 / 289 (1.04%) 3	1 / 284 (0.35%) 1
Investigations			
Cardiac murmur subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Blood immunoglobulin e increased subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Injury, poisoning and procedural complications			
Head injury subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	1 / 284 (0.35%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Laceration subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Limb injury subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	1 / 284 (0.35%) 1
Mouth injury			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Concussion			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Accidental exposure			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Skeletal injury			
subjects affected / exposed	0 / 300 (0.00%)	2 / 289 (0.69%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	0 / 300 (0.00%)	16 / 289 (5.54%)	11 / 284 (3.87%)
occurrences (all)	0	16	11
Clavicle fracture			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Exposure to toxic agent			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Nicotine poisoning			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Brain contusion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
21-hydroxylase deficiency			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Cryptorchism			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences (all)	0	1	1
Dacryostenosis congenital			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Congenital torticollis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Craniotabes			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Hereditary fructose intolerance			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Macrocephaly			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Naevus flammeus			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Pectus excavatum			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Plagiocephaly			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypokinesia			
subjects affected / exposed	2 / 300 (0.67%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	2	0	1
Pseudoparalysis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1

Hypersomnia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
High-pitched crying			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Fine motor delay			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Coordination abnormal			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	2 / 284 (0.70%)
occurrences (all)	1	0	2
Hypotonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Hypertonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Myotonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 300 (0.33%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences (all)	1	1	1
Anaemia			

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Mastocytosis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Ear and labyrinth disorders			
Middle ear effusion subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 2	1 / 284 (0.35%) 1
Middle ear disorder subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Otosalpingitis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Eye disorders			
Hypermetropia subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Strabismus subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	9 / 289 (3.11%) 9	6 / 284 (2.11%) 6
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Eyelid disorder subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Dacryostenosis acquired			

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Pupils unequal subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Dacryoadenitis acquired subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Eye inflammation subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
<b>Gastrointestinal disorders</b>			
Diarrhoea subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	4 / 289 (1.38%) 4	8 / 284 (2.82%) 8
Teething subjects affected / exposed occurrences (all)	2 / 300 (0.67%) 2	4 / 289 (1.38%) 4	3 / 284 (1.06%) 3
Vomiting subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	3 / 289 (1.04%) 3	2 / 284 (0.70%) 2
Constipation subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	2 / 284 (0.70%) 2
Flatulence subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	2 / 289 (0.69%) 2	1 / 284 (0.35%) 1
Abdominal pain subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	1 / 284 (0.35%) 1
Dental discomfort subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	1 / 284 (0.35%) 1
Dyspepsia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	2 / 289 (0.69%) 2	0 / 284 (0.00%) 0

Stomatitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	2 / 284 (0.70%)
occurrences (all)	0	0	2
Aphthous stomatitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Cheilitis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Infantile colic			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Anal prolapse			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Skin and subcutaneous tissue disorders</b>			
Neurodermatitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	1 / 300 (0.33%)	17 / 289 (5.88%)	16 / 284 (5.63%)
occurrences (all)	1	17	16
Eczema			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	5 / 284 (1.76%)
occurrences (all)	15	3	5
Eczema infantile			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	1 / 284 (0.35%)
occurrences (all)	0	3	1
Rash			

subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	3 / 284 (1.06%)
occurrences (all)	0	1	3
<b>Dermatitis</b>			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	0 / 284 (0.00%)
occurrences (all)	0	3	0
<b>Seborrhoeic dermatitis</b>			
subjects affected / exposed	2 / 300 (0.67%)	3 / 289 (1.04%)	0 / 284 (0.00%)
occurrences (all)	2	3	0
<b>Eczema asteatotic</b>			
subjects affected / exposed	0 / 300 (0.00%)	2 / 289 (0.69%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
<b>Dermatitis allergic</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
<b>Dry skin</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
<b>Intertrigo</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
<b>Rash generalised</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
<b>Xeroderma</b>			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
<b>Heat rash</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Dermatitis atopic</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Hirsutism</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Hyperhidrosis</b>			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Rash neonatal			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Skin induration			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Dose 1 and Toddler dose			
Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.			
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[22]</sup>	0 / 300 (0.00%)	110 / 206 (53.40%)	96 / 185 (51.89%)
occurrences (all)	0	110	96
Tenderness (Significant) Dose 1 and Toddler dose			
Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.			
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed <sup>[23]</sup>	0 / 300 (0.00%)	19 / 176 (10.80%)	20 / 158 (12.66%)
occurrences (all)	0	19	20
Induration (Any) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[24]</sup>	0 / 300 (0.00%)	70 / 190 (36.84%)	77 / 176 (43.75%)
occurrences (all)	0	70	77
Induration (Mild) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[25]</sup>	0 / 300 (0.00%)	62 / 186 (33.33%)	70 / 172 (40.70%)
occurrences (all)	0	62	70
Induration (Moderate) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[26]</sup>	0 / 300 (0.00%)	21 / 174 (12.07%)	20 / 158 (12.66%)
occurrences (all)	0	21	20
Erythema (Any) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[27]</sup>	0 / 300 (0.00%)	93 / 196 (47.45%)	103 / 184 (55.98%)
occurrences (all)	0	93	103
Erythema (Mild) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[28]</sup>	0 / 300 (0.00%)	85 / 191 (44.50%)	95 / 180 (52.78%)
occurrences (all)	0	85	95
Erythema (Moderate) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed <sup>[29]</sup>	0 / 300 (0.00%)	20 / 173 (11.56%)	24 / 158 (15.19%)
occurrences (all)	0	20	24
Erythema (Severe) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[30]</sup>	0 / 300 (0.00%)	0 / 166 (0.00%)	1 / 153 (0.65%)
occurrences (all)	0	0	1
Tenderness (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[31]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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 ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[32]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[33]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[34]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed <sup>[35]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[36]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[37]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: lo 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[38]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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 ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[39]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (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 ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed <sup>[40]</sup>	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed <sup>[41]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Induration (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[42]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Induration (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[43]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Erythema (Any) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[44]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Erythema (Mild) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[45]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Erythema (Moderate) Dose 3	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[46]</sup> occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Renal and urinary disorders Urinary tract disorder subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0

Ureteric stenosis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Vesicoureteric reflux subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Pain in extremity subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Joint range of motion decreased subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	1 / 284 (0.35%) 1
Foot deformity subjects affected / exposed occurrences (all)	2 / 300 (0.67%) 2	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Posture abnormal subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Arthropathy subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Exostosis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Head deformity subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Hypotonia neonatal subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	40 / 289 (13.84%) 43	32 / 284 (11.27%) 34
Bronchitis			

subjects affected / exposed	2 / 300 (0.67%)	20 / 289 (6.92%)	19 / 284 (6.69%)
occurrences (all)	2	22	19
Rhinitis			
subjects affected / exposed	0 / 300 (0.00%)	16 / 289 (5.54%)	13 / 284 (4.58%)
occurrences (all)	0	16	15
Nasopharyngitis			
subjects affected / exposed	1 / 300 (0.33%)	10 / 289 (3.46%)	14 / 284 (4.93%)
occurrences (all)	1	10	16
Otitis media			
subjects affected / exposed	0 / 300 (0.00%)	12 / 289 (4.15%)	10 / 284 (3.52%)
occurrences (all)	0	12	10
Viral infection			
subjects affected / exposed	0 / 300 (0.00%)	5 / 289 (1.73%)	8 / 284 (2.82%)
occurrences (all)	0	5	8
Febrile infection			
subjects affected / exposed	1 / 300 (0.33%)	7 / 289 (2.42%)	5 / 284 (1.76%)
occurrences (all)	1	7	5
Croup infectious			
subjects affected / exposed	0 / 300 (0.00%)	2 / 289 (0.69%)	3 / 284 (1.06%)
occurrences (all)	0	2	3
Exanthema subitum			
subjects affected / exposed	0 / 300 (0.00%)	3 / 289 (1.04%)	1 / 284 (0.35%)
occurrences (all)	0	3	1
Oral candidiasis			
subjects affected / exposed	1 / 300 (0.33%)	1 / 289 (0.35%)	3 / 284 (1.06%)
occurrences (all)	1	1	3
Pharyngitis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	3 / 284 (1.06%)
occurrences (all)	0	1	3
Candida nappy rash			
subjects affected / exposed	1 / 300 (0.33%)	2 / 289 (0.69%)	1 / 284 (0.35%)
occurrences (all)	1	2	1
Tonsillitis			
subjects affected / exposed	0 / 300 (0.00%)	2 / 289 (0.69%)	1 / 284 (0.35%)
occurrences (all)	0	2	1
Acute tonsillitis			

subjects affected / exposed	0 / 300 (0.00%)	2 / 289 (0.69%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Enteritis infectious			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences (all)	0	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	1 / 284 (0.35%)
occurrences (all)	0	1	1
Bronchitis viral			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Bronchopneumonia			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Candidiasis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Gastroenteritis norovirus			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Herpes virus infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Infection			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Omphalitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Pseudocroup			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Rhinolaryngitis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Rotavirus infection			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Scarlet fever			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Tinea infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Tracheitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Tracheobronchitis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 289 (0.35%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Viral skin infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	1	0	1
Salmonellosis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	1 / 300 (0.33%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Bacterial rhinitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Eczema infected			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Otitis media viral			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Sinobronchitis			

subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Tonsillitis streptococcal</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Urinary tract infection</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Viral diarrhoea</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Viral rhinitis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Burns second degree</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Skin candida</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	2 / 284 (0.70%)
occurrences (all)	0	0	2
<b>Periorbital cellulitis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Pharyngotonsillitis</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Gastroenteritis rotavirus</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Metabolism and nutrition disorders</b>			
<b>Feeding disorder neonatal</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
<b>Hyperphosphatasaemia</b>			
subjects affected / exposed	0 / 300 (0.00%)	0 / 289 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1

Weight gain poor subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	2 / 284 (0.70%) 2
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 289 (0.35%) 1	0 / 284 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Acidosis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Failure to thrive subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Obesity subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Oral intake reduced subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0
Metabolic acidosis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 289 (0.00%) 0	0 / 284 (0.00%) 0

<b>Non-serious adverse events</b>	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by non-serious adverse events subjects affected / exposed	11 / 287 (3.83%)	8 / 287 (2.79%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Haemangioma subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Melanocytic naevus			

subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injection site erythema			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injection site swelling			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injection site pain			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injection site induration			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Irritability			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Developmental delay			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Granuloma			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injection site haematoma			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injection site reaction			
subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Pain			

subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Fever ≥38°C but ≤39°C Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[2]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Fever >39°C but ≤40°C Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[3]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Fever >40°C Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[4]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Decreased appetite Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[5]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Irritability Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[6]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Increased sleep Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed <sup>[7]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Decreased sleep Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[8]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Fever ≥38°C but ≤39°C Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[9]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 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 ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[10]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Decreased appetite Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[11]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Irritability Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed <sup>[12]</sup> occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Increased sleep Dose 2	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

<p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[13]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Decreased sleep Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[14]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Fever <math>\geq 38^{\circ}\text{C}</math> but <math>\leq 39^{\circ}\text{C}</math> Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[15]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Fever <math>&gt; 39^{\circ}\text{C}</math> but <math>\leq 40^{\circ}\text{C}</math> Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[16]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Fever <math>&gt; 40^{\circ}\text{C}</math> Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[17]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Decreased appetite Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[18]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Irritability Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p>			

<p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[19]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Increased sleep Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[20]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Decreased sleep Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[21]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Immune system disorders</p> <p>Drug hypersensitivity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>1 / 287 (0.35%)</p> <p>1</p>	
<p>Food allergy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>1 / 287 (0.35%)</p> <p>1</p>	
<p>Atopy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Hypersensitivity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Reproductive system and breast disorders</p> <p>Balanitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Vulval disorder</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	

Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 287 (0.35%)	1 / 287 (0.35%)	
occurrences (all)	1	1	
Bronchial hyperreactivity			
subjects affected / exposed	1 / 287 (0.35%)	1 / 287 (0.35%)	
occurrences (all)	1	1	
Tonsillar disorder			
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Bronchial obstruction			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Obstructive airways disorder			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Stridor			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Supraclavicular retraction			

subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Wheezing subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Sleep disorder subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Screaming subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Agitation subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Crying subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Restlessness subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Investigations			
Cardiac murmur subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	1 / 287 (0.35%) 1	
Blood immunoglobulin e increased subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
Weight decreased subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Injury, poisoning and procedural complications			

Head injury		
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)
occurrences (all)	1	0
Contusion		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Laceration		
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)
occurrences (all)	1	0
Limb injury		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Mouth injury		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Thermal burn		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Concussion		
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)
occurrences (all)	1	0
Arthropod bite		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Accidental exposure		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Skeletal injury		
subjects affected / exposed	0 / 287 (0.00%)	2 / 287 (0.70%)
occurrences (all)	0	2
Gastroenteritis		
subjects affected / exposed	3 / 287 (1.05%)	3 / 287 (1.05%)
occurrences (all)	3	3
Clavicle fracture		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0

Exposure to toxic agent subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Nicotine poisoning subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Brain contusion subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
<b>Congenital, familial and genetic disorders</b>			
21-hydroxylase deficiency subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
Cryptorchism subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Dacryostenosis congenital subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Congenital torticollis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Cranio-tabes subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Hereditary fructose intolerance subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Macrocephaly subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Naevus flammeus subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Pectus excavatum			

subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Plagiocephaly subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Nervous system disorders			
Hypokinesia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Pseudoparalysis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Hypersomnia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
High-pitched crying subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Fine motor delay subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Coordination abnormal subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Hypotonia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Hypertonia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Myotonia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	

Somnolence subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Febrile convulsion subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	2 / 287 (0.70%) 3	
Blood and lymphatic system disorders Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Anaemia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Mastocytosis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Ear and labyrinth disorders Middle ear effusion subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Middle ear disorder subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Ear pain subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Otosalpingitis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Eye disorders Hypermetropia subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
Strabismus subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Conjunctivitis			

subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Eyelid disorder subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Dacryostenosis acquired subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Pupils unequal subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Dacryoadenitis acquired subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Eye inflammation subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
Teething subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Vomiting subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Constipation subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Flatulence subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	

Abdominal pain			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Dental discomfort			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Aphthous stomatitis			
subjects affected / exposed	0 / 287 (0.00%)	1 / 287 (0.35%)	
occurrences (all)	0	1	
Cheilitis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Enteritis			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Infantile colic			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Anal prolapse			
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)	
occurrences (all)	0	0	
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 287 (0.00%)	1 / 287 (0.35%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Neurodermatitis			
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)	
occurrences (all)	1	0	
Dermatitis diaper			

subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Eczema		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Eczema infantile		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rash		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Dermatitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Seborrhoeic dermatitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Eczema asteatotic		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Dermatitis allergic		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Dry skin		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Intertrigo		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rash generalised		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Xeroderma		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Heat rash		

subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Dermatitis atopic		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Hirsutism		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Hyperhidrosis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Petechiae		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rash maculo-papular		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rash neonatal		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rash papular		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Skin exfoliation		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Skin induration		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Urticaria		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Vitiligo		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Tenderness (Any) Dose 1 and	Additional description: Dose 1: Subjects affected and occurrences for LR is same	

<p>Toddler dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[22]</sup></p> <p>occurrences (all)</p>	<p>as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>	
	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>
<p>Tenderness (Significant) Dose 1 and Toddler dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[23]</sup></p> <p>occurrences (all)</p>	<p>Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>	
	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>
<p>Induration (Any) Dose 1 and Toddler dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[24]</sup></p> <p>occurrences (all)</p>	<p>Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>	
	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>
<p>Induration (Mild) Dose 1 and Toddler dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[25]</sup></p> <p>occurrences (all)</p>	<p>Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>	
	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>
<p>Induration (Moderate) Dose 1 and Toddler dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[26]</sup></p> <p>occurrences (all)</p>	<p>Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>	
	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>
<p>Erythema (Any) Dose 1 and Toddler dose</p> <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[27]</sup></p> <p>occurrences (all)</p>	<p>Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>	
	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>
<p>Erythema (Mild) Dose 1 and Toddler</p>	<p>Additional description: Dose 1: Subjects affected and occurrences for LR is same</p>	

dose	as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[28]</sup></p> <p>occurrences (all)</p>	0 / 287 (0.00%)	0 / 287 (0.00%)
Erythema (Moderate) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[29]</sup></p> <p>occurrences (all)</p>	0 / 287 (0.00%)	0 / 287 (0.00%)
Erythema (Severe) Dose 1 and Toddler dose	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[30]</sup></p> <p>occurrences (all)</p>	0 / 287 (0.00%)	0 / 287 (0.00%)
Tenderness (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[31]</sup></p> <p>occurrences (all)</p>	0 / 287 (0.00%)	0 / 287 (0.00%)
Tenderness (Significant) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[32]</sup></p> <p>occurrences (all)</p>	0 / 287 (0.00%)	0 / 287 (0.00%)
Induration (Any) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[33]</sup></p> <p>occurrences (all)</p>	0 / 287 (0.00%)	0 / 287 (0.00%)
Induration (Mild) Dose 2	Additional description: Dose 2: Subjects affected and occurrences for LR is same	

<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[34]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>
<p>Induration (Moderate) Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[35]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Erythema (Any) Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[36]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Erythema (Mild) Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[37]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Erythema (Moderate) Dose 2</p>	<p>Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: lo 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[38]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Tenderness (Any) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>		
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[39]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Tenderness (Significant) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same</p>		

<p>alternative dictionary used: Local Reactions 0.0  alternative assessment type: Systematic  subjects affected / exposed<sup>[40]</sup>  occurrences (all)</p>	<p>as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p> <table border="1"> <tr> <td data-bbox="654 224 901 347">0 / 287 (0.00%) 0</td> <td data-bbox="901 224 1165 347">0 / 287 (0.00%) 0</td> <td data-bbox="1165 224 1428 347"></td> </tr> </table>	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
0 / 287 (0.00%) 0	0 / 287 (0.00%) 0			
<p>Induration (Any) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>			
<p>alternative dictionary used: Local Reactions 0.0  alternative assessment type: Systematic  subjects affected / exposed<sup>[41]</sup>  occurrences (all)</p>	<table border="1"> <tr> <td data-bbox="654 571 901 694">0 / 287 (0.00%) 0</td> <td data-bbox="901 571 1165 694">0 / 287 (0.00%) 0</td> <td data-bbox="1165 571 1428 694"></td> </tr> </table>	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
0 / 287 (0.00%) 0	0 / 287 (0.00%) 0			
<p>Induration (Mild) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>			
<p>alternative dictionary used: Local Reactions 0.0  alternative assessment type: Systematic  subjects affected / exposed<sup>[42]</sup>  occurrences (all)</p>	<table border="1"> <tr> <td data-bbox="654 907 901 1030">0 / 287 (0.00%) 0</td> <td data-bbox="901 907 1165 1030">0 / 287 (0.00%) 0</td> <td data-bbox="1165 907 1428 1030"></td> </tr> </table>	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
0 / 287 (0.00%) 0	0 / 287 (0.00%) 0			
<p>Induration (Moderate) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>			
<p>alternative dictionary used: Local Reactions 0.0  alternative assessment type: Systematic  subjects affected / exposed<sup>[43]</sup>  occurrences (all)</p>	<table border="1"> <tr> <td data-bbox="654 1254 901 1377">0 / 287 (0.00%) 0</td> <td data-bbox="901 1254 1165 1377">0 / 287 (0.00%) 0</td> <td data-bbox="1165 1254 1428 1377"></td> </tr> </table>	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
0 / 287 (0.00%) 0	0 / 287 (0.00%) 0			
<p>Erythema (Any) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>			
<p>alternative dictionary used: Local Reactions 0.0  alternative assessment type: Systematic  subjects affected / exposed<sup>[44]</sup>  occurrences (all)</p>	<table border="1"> <tr> <td data-bbox="654 1601 901 1724">0 / 287 (0.00%) 0</td> <td data-bbox="901 1601 1165 1724">0 / 287 (0.00%) 0</td> <td data-bbox="1165 1601 1428 1724"></td> </tr> </table>	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
0 / 287 (0.00%) 0	0 / 287 (0.00%) 0			
<p>Erythema (Mild) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>			
<p>alternative dictionary used: Local Reactions 0.0  alternative assessment type: Systematic  subjects affected / exposed<sup>[45]</sup>  occurrences (all)</p>	<table border="1"> <tr> <td data-bbox="654 1937 901 2060">0 / 287 (0.00%) 0</td> <td data-bbox="901 1937 1165 2060">0 / 287 (0.00%) 0</td> <td data-bbox="1165 1937 1428 2060"></td> </tr> </table>	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
0 / 287 (0.00%) 0	0 / 287 (0.00%) 0			
<p>Erythema (Moderate) Dose 3</p>	<p>Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p>			

as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[46]</sup></p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Renal and urinary disorders</p> <p>Urinary tract disorder</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Ureteric stenosis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vesicoureteric reflux</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 287 (0.00%)</p> <p>0</p> <p>0 / 287 (0.00%)</p> <p>0</p> <p>1 / 287 (0.35%)</p> <p>1</p>	<p>0 / 287 (0.00%)</p> <p>0</p> <p>0 / 287 (0.00%)</p> <p>0</p> <p>0 / 287 (0.00%)</p> <p>0</p>	
<p>Musculoskeletal and connective tissue disorders</p> <p>Pain in extremity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Joint range of motion decreased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Foot deformity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Posture abnormal</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Arthropathy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Exostosis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Head deformity</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	<p>0 / 287 (0.00%)</p> <p>0</p>	

subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Hypotonia neonatal subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
<b>Infections and infestations</b>			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Bronchitis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Rhinitis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Otitis media subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
Viral infection subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Febrile infection subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Croup infectious subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Exanthema subitum subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	

Pharyngitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Candida nappy rash		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Tonsillitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Acute tonsillitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Enteritis infectious		
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)
occurrences (all)	1	0
Influenza		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Bronchitis viral		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Bronchopneumonia		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Candidiasis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Fungal infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Fungal skin infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0

Gastroenteritis norovirus		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Gastroenteritis viral		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Herpes virus infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Lower respiratory tract infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Omphalitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Oral fungal infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Otitis externa		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Otitis media acute		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Paronychia		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Pneumonia		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Pseudocroup		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0

Respiratory tract infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Respiratory tract infection viral		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rhinolaryngitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Rotavirus infection		
subjects affected / exposed	0 / 287 (0.00%)	1 / 287 (0.35%)
occurrences (all)	0	1
Scarlet fever		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Tinea infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Tracheitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Tracheobronchitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Viral skin infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Wound infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Salmonellosis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Varicella		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0

Ear infection		
subjects affected / exposed	0 / 287 (0.00%)	1 / 287 (0.35%)
occurrences (all)	0	1
Bacterial infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Bronchiolitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Genital candidiasis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Viral rash		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Abscess		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Bacterial rhinitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Bronchitis bacterial		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Conjunctivitis infective		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Eczema infected		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Folliculitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Gastrointestinal infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0

Otitis media viral		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Pertussis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Postoperative wound infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Sinobronchitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Tonsillitis streptococcal		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Urinary tract infection		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Viral diarrhoea		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Viral rhinitis		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Burns second degree		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Skin candida		
subjects affected / exposed	0 / 287 (0.00%)	0 / 287 (0.00%)
occurrences (all)	0	0
Periorbital cellulitis		
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)
occurrences (all)	1	0
Pharyngotonsillitis		
subjects affected / exposed	1 / 287 (0.35%)	0 / 287 (0.00%)
occurrences (all)	1	0

Gastroenteritis rotavirus subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	3 / 287 (1.05%) 3	
Metabolism and nutrition disorders			
Feeding disorder neonatal subjects affected / exposed occurrences (all)	1 / 287 (0.35%) 1	0 / 287 (0.00%) 0	
Hyperphosphatasaemia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	1 / 287 (0.35%) 1	
Weight gain poor subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Decreased appetite subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Dehydration subjects affected / exposed occurrences (all)	2 / 287 (0.70%) 2	1 / 287 (0.35%) 1	
Acidosis subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Failure to thrive subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Obesity subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Oral intake reduced subjects affected / exposed occurrences (all)	0 / 287 (0.00%) 0	0 / 287 (0.00%) 0	
Metabolic acidosis			







## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported