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

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

Summary

EudraCT number	2008-004765-26
Trial protocol	Outside EU/EEA
Global end of trial date	04 May 2009

Results information

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

Trial information

Trial identification

Sponsor protocol code	6096A1-3008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00475033
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851008

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 February 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 May 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that immune response induced by meningococcal group C conjugate vaccine (NeisVac-C) given with 13vPnC is noninferior to the immune response induced by NeisVac-C given with 7 valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the 2-dose NeisVac-C infant series.
To demonstrate that immune responses induced by Pentacel given with 13vPnC are noninferior to immune responses induced by Pentacel given with 7vPnC when measured 1 month after 3-dose infant series. The immune responses to the following antigens in Pentacel will be assessed: pertussis antigens (pertussis toxoid [PT], filamentous haemagglutinin [FHA], pertactin [PRN], and fimbrial agglutinogens [FIM]) and Haemophilus influenzae type b (Hib).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 June 2007
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	Canada: 603
Worldwide total number of subjects	603
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	603
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 Canada from June 2007 through November 2007.

Pre-assignment

Screening details:

A total of 608 subjects were screened out of which 603 subjects were randomly assigned in a 1:1 ratio to either 13vPnC group (n=300) or the 7vPnC group (n=303).

Period 1

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

Arms

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

Arm description:

Subjects received 13vPnC at 2, 4, and 6 months of age (infant series) co-administered with Pentacel (a commercially available combination diphtheria, tetanus, acellular pertussis, inactivated polio, aluminium and Hib conjugate vaccine) at 2, 4, and 6 months of age; NeisVac-C (a commercially available meningococcal C tetanus toxoid conjugate vaccine) at 2 and 6 months of age (infant series).

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

Dosage and administration details:

Subjects received 1 single 0.5 milliliter (mL) dose of 13vPnC at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of Pentacel at 2, 4 and 6 months of age (infant series).

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of NeisVac-C at 2 and 6 months of age (infant series).

Arm title	7vPnC Infant Series

Arm description:

Subjects received 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series) co-administered with Pentacel (a commercially available combination diphtheria, tetanus, acellular pertussis, inactivated polio, aluminium and Hib conjugate vaccine) at 2, 4, and 6 months of

age; NeisVac-C (a commercially available meningococcal C tetanus toxoid conjugate vaccine) at 2 and 6 months of age (infant series).

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of 7vPnC at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of Pentacel at 2, 4, and 6 months of age (infant series).

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of NeisVac-C at 2 and 6 months of age (infant series).

Number of subjects in period 1	13vPnC Infant Series	7vPnC Infant Series
Started	300	303
Vaccinated Dose 1	300	303
Vaccinated Dose 2	297	296
Vaccinated Dose 3	293	294
Completed	293	291
Not completed	7	12
Parent or legal guardian request	1	5
Failed to return	3	4
Adverse Event	-	1
Protocol Violation	1	2
Lost to follow-up	2	-

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
Arm title	13vPnC After the Infant Series

Arm description:

Included subjects who received 13vPnC co-administered with Pentacel at 2, 4, and 6 months of age (infant series); NeisVac-C at 2 and 6 months of age (infant series).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC After the Infant Series

Arm description:

Included subjects who received 7vPnC co-administered with Pentacel at 2, 4, and 6 months of age (infant series); NeisVac-C at 2 and 6 months of age (infant series).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC After the Infant Series	7vPnC After the Infant Series
Started	293	291
Completed	287	282
Not completed	6	9
Parent or legal guardian request	2	2
Failed to return	2	1
Adverse Event	-	4
Protocol Violation	1	-
Unspecified	-	2
Lost to follow-up	1	-

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

Arms	
Are arms mutually exclusive?	Yes

Arm title	13vPnC Toddler Dose

Arm description:

Subjects received 13vPnC co-administered with NeisVac-C at 12 months of age (toddler dose); a single type of commercially available Measles, Mumps, and Rubella vaccine (MMR) at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of 13vPnC at 12 months of age (toddler dose).

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of NeisVac-C at 12 months of age (toddler dose).

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of MMR at 12 months of age (toddler dose).

Investigational medicinal product name	Varivax III
Investigational medicinal product code	
Other name	Varicella vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of varicella vaccine at 12 months of age (toddler dose).

Arm title	7vPnC Toddler Dose

Arm description:

Subjects received 7vPnC co-administered with NeisVac-C at 12 months of age (toddler dose); a single type of commercially available MMR at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of 7vPnC at 12 months of age (toddler dose).

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details: Subjects received 1 single 0.5 mL dose of NeisVac-C at 12 months of age (toddler dose).	
Investigational medicinal product name	MMR II
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects received 1 single 0.5 mL dose of MMR at 12 months of age (toddler dose).	
Investigational medicinal product name	Varivax III
Investigational medicinal product code	
Other name	Varicella vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects received 1 single 0.5 mL dose of varicella vaccine at 12 months of age (toddler dose).	

Number of subjects in period 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	287	282
Completed	283	282
Not completed	4	0
Parent or legal guardian request	2	-
Failed to return	1	-
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC Infant Series
Reporting group description:	
Subjects received 13vPnC at 2, 4, and 6 months of age (infant series) co-administered with Pentacel (a commercially available combination diphtheria, tetanus, acellular pertussis, inactivated polio, aluminium and Hib conjugate vaccine) at 2, 4, and 6 months of age; NeisVac-C (a commercially available meningococcal C tetanus toxoid conjugate vaccine) at 2 and 6 months of age (infant series).	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Subjects received 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series) co-administered with Pentacel (a commercially available combination diphtheria, tetanus, acellular pertussis, inactivated polio, aluminium and Hib conjugate vaccine) at 2, 4, and 6 months of age; NeisVac-C (a commercially available meningococcal C tetanus toxoid conjugate vaccine) at 2 and 6 months of age (infant series).	

Reporting group values	13vPnC Infant Series	7vPnC Infant Series	Total
Number of subjects	300	303	603
Age categorical			
Units: Subjects			
Age continuous			
Units: months			
arithmetic mean	2.1	2.1	
standard deviation	± 0.3	± 0.3	-
Gender categorical			
Units: Subjects			
Female	143	152	295
Male	157	151	308

End points

End points reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description:	
Subjects received 13vPnC at 2, 4, and 6 months of age (infant series) co-administered with Pentacel (a commercially available combination diphtheria, tetanus, acellular pertussis, inactivated polio, aluminium and Hib conjugate vaccine) at 2, 4, and 6 months of age; NeisVac-C (a commercially available meningococcal C tetanus toxoid conjugate vaccine) at 2 and 6 months of age (infant series).	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Subjects received 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series) co-administered with Pentacel (a commercially available combination diphtheria, tetanus, acellular pertussis, inactivated polio, aluminium and Hib conjugate vaccine) at 2, 4, and 6 months of age; NeisVac-C (a commercially available meningococcal C tetanus toxoid conjugate vaccine) at 2 and 6 months of age (infant series).	
Reporting group title	13vPnC After the Infant Series
Reporting group description:	
Included subjects who received 13vPnC co-administered with Pentacel at 2, 4, and 6 months of age (infant series); NeisVac-C at 2 and 6 months of age (infant series).	
Reporting group title	7vPnC After the Infant Series
Reporting group description:	
Included subjects who received 7vPnC co-administered with Pentacel at 2, 4, and 6 months of age (infant series); NeisVac-C at 2 and 6 months of age (infant series).	
Reporting group title	13vPnC Toddler Dose
Reporting group description:	
Subjects received 13vPnC co-administered with NeisVac-C at 12 months of age (toddler dose); a single type of commercially available Measles, Mumps, and Rubella vaccine (MMR) at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.	
Reporting group title	7vPnC Toddler Dose
Reporting group description:	
Subjects received 7vPnC co-administered with NeisVac-C at 12 months of age (toddler dose); a single type of commercially available MMR at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.	

Primary: Percentage of Subjects Achieving Predefined Antibody Level Greater than or Equal to (≥) 1:8 for Meningococcal C Serum Bactericidal Assay (SBA) in the 13vPnC Group Relative to 7vPnC Group After 2 Doses of NeisVac-C in the Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level Greater than or Equal to (≥) 1:8 for Meningococcal C Serum Bactericidal Assay (SBA) in the 13vPnC Group Relative to 7vPnC Group After 2 Doses of NeisVac-C in the Infant Series
End point description:	
Percentage of subjects achieving predefined antibody threshold ≥1:8 along with the corresponding 95 percent (%) confidence interval (CI) for concomitant antigen meningococcal C SBA are presented. Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups >-10%. Evaluable immunogenicity population: had treatments as randomized at all expected doses, blood drawn within specified timeframes, at least 1 valid and determinate assay result for proposed analysis, and no major protocol violations.	
End point type	Primary
End point timeframe:	
1 month after 2 doses of NeisVac-C in the infant series (7 months of age)	

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	284[1]	278[2]		
Units: Percentage of subjects				
number (confidence interval 95%)	96.8 (94.1 to 98.5)	99.3 (97.4 to 99.9)		

Notes:

[1] - Subjects analyzed with a determinate post-infant series antibody concentration to the given antigen.
[2] - Subjects analyzed with a determinate post-infant series antibody concentration to the given antigen.

Statistical analyses

Statistical analysis title	Analysis of Subjects With Meningococcal C antibody
Statistical analysis description:	
Meningococcal C: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	562
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	-0.1

Notes:

[3] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Primary: Geometric Mean Titer (GMT) of Meningococcal C Antigen in the 13vPnC Group Relative to 7vPnC Group After 2 Doses of NeisVac-C in the Infant Series

End point title	Geometric Mean Titer (GMT) of Meningococcal C Antigen in the 13vPnC Group Relative to 7vPnC Group After 2 Doses of NeisVac-C in the Infant Series

End point description:

Antibody geometric mean titer of meningococcal C antigen are presented. GMT and corresponding 2-sided 95% CI were constructed by back transformation of the CI for the mean of the logarithmically transformed assay results computed using the Student t distribution. In addition, the 2-sided 95% confidence interval on the ratio of the geometric means for 13vPnC relative to 7vPnC was constructed by back transformation of the Student t distribution for the mean difference of the measures on the logarithmic scale. The evaluable immunogenicity population was the primary analysis population. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw.

End point type	Primary

End point timeframe:

1 month after 2 doses of NeisVac-C in the infant series (7 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	284[4]	278[5]		
Units: GMT				
geometric mean (confidence interval 95%)	361.16 (305.46 to 427)	302.55 (263.89 to 346.86)		

Notes:

[4] - Subjects analyzed with a determinate antibody titer to the given antigen.

[5] - Subjects analyzed with a determinate antibody titer to the given antigen.

Statistical analyses

Statistical analysis title	Analysis of GMT for Meningococcal C

Statistical analysis description:

Ratio of GMs (13vPnC, 7vPnC). CI for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC, 7vPnC).

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	562
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Ratio of geometric means
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.48

Notes:

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

Primary: Percentage of Subjects Achieving Predefined Antibody Level to Pertussis Antigens in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level to Pertussis Antigens in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point description:

Percentage of subjects achieving predefined antibody threshold >=5 enzyme-linked immunosorbent assay (ELISA) units per mL (EU/mL) along with the corresponding 95 % CI for concomitant antigens pertussis (PT, FHA, and PRN and ≥ 2.2 EU/mL FIM) are presented. Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups > -10%. The evaluable immunogenicity population was the primary analysis population; (n)=number of subjects with an antibody concentration (titer) ≥ to prespecified level for the given antigen for 13vPnC and 7vPnC, respectively.

End point type	Primary

End point timeframe:

1 month after the 3-dose infant series (7 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	278		
Units: percentage of subjects				
number (confidence interval 95%)				
PT ≥5 EU/mL (n=282, 277)	99.6 (98 to 100)	99.6 (98 to 100)		
FHA ≥5 EU/mL (n=283, 278)	100 (98.7 to 100)	100 (98.7 to 100)		
PRN ≥5 EU/mL (n=283, 277)	97.9 (95.4 to 99.2)	96.8 (93.9 to 98.5)		
FIM ≥2.2 EU/mL (n=282, 275)	95.4 (92.2 to 97.5)	97.5 (94.8 to 99)		

Statistical analyses

Statistical analysis title	Analysis for PT
Statistical analysis description:	
PT: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.7

Notes:

[7] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Statistical analysis title	Analysis for FHA
Statistical analysis description:	
FHA: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

Notes:

[8] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Statistical analysis title	Analysis for PRN

Statistical analysis description:

PRN: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Difference
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	4.2

Notes:

[9] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Statistical analysis title	Analysis for FIM

Statistical analysis description:

FIM: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Parameter estimate	Difference
Point estimate	-2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	1.2

Notes:

[10] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Primary: Geometric Mean Concentration (GMC) of Pertussis Antigens in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point title	Geometric Mean Concentration (GMC) of Pertussis Antigens in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point description:

Antibody GMC of pertussis antigens (PT, FHA, PRN, and FIM) as measured by EU/mL are presented.

GMC and corresponding 2-sided 95% CI were constructed by back transformation of the CI for the mean of the logarithmically transformed assay results computed using the Student t distribution. In addition, the 2-sided 95% confidence intervals on the ratio of the GMCs for 13vPnC relative to 7vPnC were constructed by back transformation of the Student t distribution for the mean difference of the measures on the logarithmic scale. The evaluable immunogenicity population was the primary analysis population; (n)=number of subjects with a determinate antibody concentration (titer) to the given antigen. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw.

End point type	Primary

End point timeframe:

1 month after the 3-dose infant Series (7 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	278		
Units: GMC EU/mL				
geometric mean (confidence interval 95%)				
PT (n=282, 277)	46.06 (42.83 to 49.53)	40.37 (37.24 to 43.75)		
FHA (n=283, 278)	78.08 (72.47 to 84.13)	69.52 (64.39 to 75.05)		
PRN (n=283, 277)	42.9 (38.17 to 48.22)	40.69 (36.16 to 45.79)		
FIM (n=282, 275)	11.54 (10.48 to 12.71)	12.98 (11.81 to 14.27)		

Statistical analyses

Statistical analysis title	Analysis of GMC for PT

Statistical analysis description:

PT: Ratio of geometric means (13vPnC, 7vPnC).

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	Ratio of geometric means
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.27

Notes:

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

Statistical analysis title	Analysis of GMC for FHA

Statistical analysis description:

FHA: Ratio of geometric means (13vPnC, 7vPnC). CI for the ratio were back transformations of a CI

based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC, 7vPnC).

Comparison groups	7vPnC Infant Series v 13vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
Parameter estimate	Ratio of geometric means
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.25

Notes:

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

Statistical analysis title	Analysis of GMC for PRN

Statistical analysis description:

PRN: Ratio of geometric means (13vPnC, 7vPnC). CI for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC, 7vPnC).

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	Ratio of geometric means
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.24

Notes:

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

Statistical analysis title	Analysis of GMC for FIM

Statistical analysis description:

FIM: Ratio of geometric means (13vPnC, 7vPnC). CI for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC, 7vPnC).

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
Parameter estimate	Ratio of geometric means
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.02

Notes:

[14] - Noninferiority 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 Predefined Antibody Level ≥0.15 Micrograms Per mL (µg/mL) for Polyribosylribitol Phosphate (PRP) in Hib in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level ≥0.15 Micrograms Per mL (µg/mL) for Polyribosylribitol Phosphate (PRP) in Hib in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point description:

Percentage of subjects achieving predefined antibody threshold ≥0.15 µg/mL along with the corresponding 95 percent (%) confidence interval (CI) for concomitant antigen PRP in Hib are presented. Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups > -10%. The evaluable immunogenicity population was the primary analysis population.

End point type	Primary

End point timeframe:

1 month after the 3-dose Infant Series (7 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272[15]	266[16]		
Units: percentage of subjects				
number (confidence interval 95%)	97.8 (95.3 to 99.2)	99.6 (97.9 to 100)		

Notes:

[15] - Subjects analyzed with a determinate post-infant series antibody concentration to the given antigen.
[16] - Subjects analyzed with a determinate post-infant series antibody concentration to the given antigen.

Statistical analyses

Statistical analysis title	Analysis for PRP in Hib

Statistical analysis description:

Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	538
Analysis specification	Pre-specified
Analysis type	non-inferiority[17]
Parameter estimate	Difference
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	0.1

Notes:

[17] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Primary: Geometric Mean Concentration (GMC) of PRP in Hib in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point title	Geometric Mean Concentration (GMC) of PRP in Hib in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point description:

Antibody GMC of PRP in Hib as measured by µg/mL are presented. GMC and corresponding 2-sided 95% CI were constructed by back transformation of the CI for the mean of the logarithmically transformed assay results computed using the Student t distribution. In addition, the 2-sided 95% confidence interval on the ratio of the GMCs for 13vPnC relative to 7vPnC was constructed by back transformation of the Student t distribution for the mean difference of the measures on the logarithmic scale. The evaluable immunogenicity population was the primary analysis population. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw.

End point type	Primary

End point timeframe:

1 month after the 3-dose Infant Series (7 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272[18]	266[19]		
Units: GMC µg/mL				
geometric mean (confidence interval 95%)	2.87 (2.48 to 3.32)	3.14 (2.74 to 3.6)		

Notes:

[18] - Subjects analyzed with a determinate antibody concentration (titer) to the given antigen.

[19] - Subjects analyzed with a determinate antibody concentration (titer) to the given antigen.

Statistical analyses

Statistical analysis title	Analysis of GMC for PRP in Hib

Statistical analysis description:

PRP in Hib: Ratio of geometric means (13vPnC, 7vPnC). CI for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC, 7vPnC).

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	538
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
Parameter estimate	Ratio of geometric means
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.12

Notes:

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

Secondary: Percentage of Subjects Achieving Predefined Antibody Level ≥1:8 for Meningococcal C SBA in the 13vPnC Group Relative to 7vPnC Group After the Toddler Dose of NeisVac-C

End point title	Percentage of Subjects Achieving Predefined Antibody Level ≥1:8 for Meningococcal C SBA in the 13vPnC Group Relative to 7vPnC Group After the Toddler Dose of NeisVac-C

End point description:

Percentage of subjects achieving predefined antibody threshold ≥1:8 along with the corresponding 95% CI for concomitant antigen meningococcal C SBA are presented. Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups > -10%. The evaluable immunogenicity population was the primary analysis population.

End point type	Secondary

End point timeframe:

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

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265[21]	268[22]		
Units: percentage of subjects				
number (confidence interval 95%)	100 (98.6 to 100)	100 (98.6 to 100)		

Notes:

[21] - Subjects with a determinate post-toddler dose antibody concentration (titer) to the given antigen.

[22] - Subjects with a determinate post-toddler dose antibody concentration (titer) to the given antigen.

Statistical analyses

Statistical analysis title	Antibody Level ≥1:8 for Meningococcal C SBA

Statistical analysis description:

Meningococcal C: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	13vPnC Toddler Dose v 7vPnC Toddler Dose
Number of subjects included in analysis	533
Analysis specification	Pre-specified
Analysis type	non-inferiority[23]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Notes:

[23] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Secondary: Geometric Mean Titer (GMT) of Meningococcal C Antigen in the 13vPnC Group Relative to 7vPnC Group After the Toddler Dose

End point title	Geometric Mean Titer (GMT) of Meningococcal C Antigen in the 13vPnC Group Relative to 7vPnC Group After the Toddler Dose

End point description:

Antibody geometric mean titer of meningococcal C antigen are presented. GMT and corresponding 2-

sided 95% CI were constructed by back transformation of the CI for the mean of the logarithmically transformed assay results computed using the Student t distribution. In addition, the 2-sided 95% confidence interval on the ratio of the GMs for 13vPnC relative to 7vPnC was constructed by back transformation of the Student t distribution for the mean difference of the measures on the logarithmic scale. The evaluable immunogenicity population was the primary analysis population; Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw.

End point type	Secondary

End point timeframe:

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

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265[24]	268[25]		
Units: GMT				
geometric mean (confidence interval 95%)	1379.75 (1235.06 to 1541.39)	1083.96 (962.54 to 1220.69)		

Notes:

[24] - Subjects analyzed with a determinate antibody titer to the given antigen.

[25] - Subjects analyzed with a determinate antibody titer to the given antigen.

Statistical analyses

Statistical analysis title	Analysis of GMT for Meningococcal Antigen

Statistical analysis description:

Meningococcal C: Ratio of geometric means (13vPnC, 7vPnC). CI for the ratio were back transformations of a CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC, 7vPnC).

Comparison groups	13vPnC Toddler Dose v 7vPnC Toddler Dose
Number of subjects included in analysis	533
Analysis specification	Pre-specified
Analysis type	non-inferiority[26]
Parameter estimate	Ratio of geometric means
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.08
upper limit	1.5

Notes:

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

Secondary: Percentage of Subjects Achieving Predefined Antibody Level ≥1.0 µg/mL for PRP in Hib in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level ≥1.0 µg/mL for PRP in Hib in the 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series

End point description:

Percentage of subjects achieving predefined antibody threshold ≥1.0 µg/mL along with the corresponding 95% CI for concomitant antigen PRP in Hib are presented. Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups > -10%. The

evaluable immunogenicity population was the primary analysis population.

End point type	Secondary

End point timeframe:

1 month after the 3-dose infant series (7 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272[27]	266[28]		
Units: percentage of subjects				
number (confidence interval 95%)	81.6 (76.5 to 86)	84.6 (79.7 to 88.7)		

Notes:

[27] - Subjects with a determinate post-infant series antibody concentration (titer) to the given antigen.

[28] - Subjects with a determinate post-infant series antibody concentration (titer) to the given antigen.

Statistical analyses

Statistical analysis title	Antibody Level >=1.0 µg/mL for PRP in Hib

Statistical analysis description:

PRP: Difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	538
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
Parameter estimate	Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	3.4

Notes:

[29] - Non-inferiority was declared if the lower limit of the 2-sided 95% CI for the difference between the 2 treatment groups was > -10%. Exact 2-sided CI for the difference in proportions (13vPnC, 7vPnC) expressed as a percentage.

Other pre-specified: Percentage of Subjects Achieving Pneumococcal Immunoglobulin G (IgG) Antibody Level ≥0.35 µg/mL in the 13vPnC Group After the 3-dose Infant Series

End point title	Percentage of Subjects Achieving Pneumococcal Immunoglobulin G (IgG) Antibody Level ≥0.35 µg/mL in the 13vPnC Group After the 3-dose Infant Series[30]

End point description:

Percentage of subjects achieving World Health Organization (WHO) predefined antibody threshold ≥0.35µg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. The evaluable immunogenicity population was the primary analysis population; (n)=number of subjects with a determinate IgG antibody concentration to the given serotype for 13vPnC.

End point type	Other pre-specified

End point timeframe:

1 month after the 3-dose infant series (7 months of age)

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per the end point title, data for only the 13vPnC group was meant to be reported.

End point values	13vPnC Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: percentage of subjects				
number (confidence interval 95%)				
Common serotypes - serotype 4 (n=277)	97.1 (94.4 to 98.7)			
Common serotypes - serotype 6B (n=276)	93.1 (89.5 to 95.8)			
Common serotypes - serotype 9V (n=277)	95.3 (92.1 to 97.5)			
Common serotypes - serotype 14 (n=275)	98.2 (95.8 to 99.4)			
Common serotypes - serotype 18C n=277)	96.4 (93.5 to 98.3)			
Common serotypes - serotype 19F (n=273)	98.5 (96.3 to 99.6)			
Common serotypes - serotype 23F (n=275)	90.2 (86 to 93.4)			
Additional serotypes - serotype 1 (n=277)	95.7 (92.6 to 97.7)			
Additional serotypes - serotype 3 (n=275)	79.6 (74.4 to 84.2)			
Additional serotypes - serotype 5 (n=276)	87 (82.4 to 90.7)			
Additional serotypes - serotype 6A (n=276)	96.4 (93.4 to 98.2)			
Additional serotypes - serotype 7F (n=276)	98.6 (96.3 to 99.6)			
Additional serotypes - serotype 19A (n=272)	97.8 (95.3 to 99.2)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Concentration (GMC) for Pneumococcal IgG Antibody in 13vPnC Group After the 3-dose Infant Series

End point title	Geometric Mean Concentration (GMC) for Pneumococcal IgG Antibody in 13vPnC Group After the 3-dose Infant Series[31]

End point description:

Antibody GMC as measured by µg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. 2-sided 95% CI were constructed by back transformation of the CI for the mean of the logarithmically transformed assay results computed using the Student t distribution. The evaluable immunogenicity population was the primary analysis population; (n)=number of subjects with a determinate antibody concentration for the given serotype for 13vPnC.

End point type	Other pre-specified

End point timeframe:

1 month after the 3-dose infant series (7 months of age)

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per the end point title, data for only the 13vPnC group was meant to be reported.

End point values	13vPnC Infant Series			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: GMC µg/mL				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=277)	1.46 (1.33 to 1.6)			
Common serotypes - serotype 6B (n=276)	2.16 (1.87 to 2.49)			
Common serotypes - serotype 9V (n=277)	1.12 (1.03 to 1.22)			
Common serotypes - serotype 14 (n=275)	5.43 (4.86 to 6.06)			
Common serotypes - serotype 18C n=277)	1.37 (1.23 to 1.52)			
Common serotypes - serotype 19F (n=273)	2.18 (1.99 to 2.39)			
Common serotypes - serotype 23F (n=275)	1.15 (1.03 to 1.3)			
Additional serotypes - serotype 1 (n=277)	1.82 (1.63 to 2.04)			
Additional serotypes - serotype 3 (n=275)	0.63 (0.58 to 0.7)			
Additional serotypes - serotype 5 (n=276)	0.9 (0.81 to 0.99)			
Additional serotypes - serotype 6A (n=276)	1.92 (1.73 to 2.12)			
Additional serotypes - serotype 7F (n=276)	2.26 (2.09 to 2.45)			
Additional serotypes - serotype 19A (n=272)	2 (1.82 to 2.19)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Achieving Pneumococcal Immunoglobulin G (IgG) Antibody Level ≥0.35 µg/mL in the 13vPnC Group After the Toddler Dose

End point title	Percentage of Subjects Achieving Pneumococcal Immunoglobulin G (IgG) Antibody Level ≥0.35 µg/mL in the 13vPnC Group After the Toddler Dose

End point description:

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

=number of subjects with a determinate IgG antibody concentration to the given serotype for 13vPnC.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	264			
Units: percentage of subjects				
number (confidence interval 95%)				
Common serotypes - serotype 4 (n=264)	100 (98.6 to 100)			
Common serotypes - serotype 6B (n=263)	100 (98.6 to 100)			
Common serotypes - serotype 9V (n=264)	99.2 (97.3 to 99.9)			
Common serotypes - serotype 14 (n=264)	100 (98.6 to 100)			
Common serotypes - serotype 18C (n=262)	98.9 (96.7 to 99.8)			
Common serotypes - serotype 19F (n=263)	98.1 (95.6 to 99.4)			
Common serotypes - serotype 23F (n=263)	99.6 (97.9 to 100)			
Additional serotypes - serotype 1 (n=264)	100 (98.6 to 100)			
Additional serotypes - serotype 3 (n=264)	84.8 (79.9 to 88.9)			
Additional serotypes - serotype 5 (n=264)	98.5 (96.2 to 99.6)			
Additional serotypes - serotype 6A (n=264)	100 (98.6 to 100)			
Additional serotypes - serotype 7F (n=264)	100 (98.6 to 100)			
Additional serotypes - serotype 19A (n=263)	100 (98.6 to 100)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Concentration (GMC) for Pneumococcal IgG Antibody in 13vPnC Group After the Toddler Dose

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

End point description:

Antibody GMC as measured by µg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. 2-sided 95% CI were constructed by back transformation of the CI for the mean of the logarithmically transformed assay results computed using the Student t distribution. The evaluable immunogenicity population was the primary analysis population; (n)=number of subjects with a determinate antibody

concentration for the given serotype for 13vPnC.

End point type	Other pre-specified

End point timeframe:

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

End point values	13vPnC Toddler Dose			
Subject group type	Reporting group			
Number of subjects analysed	264			
Units: GMC µg/mL				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=264)	2.67 (2.43 to 2.92)			
Common serotypes - serotype 6B (n=263)	9.83 (8.83 to 10.94)			
Common serotypes - serotype 9V (n=264)	2.04 (1.87 to 2.23)			
Common serotypes - serotype 14 (n=264)	7.58 (6.86 to 8.37)			
Common serotypes - serotype 18C (n=262)	2 (1.8 to 2.21)			
Common serotypes - serotype 19F (n=263)	5.7 (5.06 to 6.42)			
Common serotypes - serotype 23F (n=263)	3.59 (3.21 to 4.01)			
Additional serotypes - serotype 1 (n=264)	3.45 (3.11 to 3.82)			
Additional serotypes - serotype 3 (n=264)	0.74 (0.67 to 0.81)			
Additional serotypes - serotype 5 (n=264)	2.38 (2.15 to 2.62)			
Additional serotypes - serotype 6A (n=264)	6.47 (5.87 to 7.12)			
Additional serotypes - serotype 7F (n=264)	3.88 (3.59 to 4.21)			
Additional serotypes - serotype 19A (n=263)	8.36 (7.61 to 9.19)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Infant Series Dose 1 (2 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Infant Series Dose 1 (2 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety

population: all subjects who received at least 1 dose of study vaccine. (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (2 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	284[32]	284[33]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=281, 283)	44.5	43.8		
Tenderness: Significant (n=270, 274)	4.4	4		
Induration: Any (n=271, 276)	5.9	7.2		
Induration: Mild (n=270, 275)	5.6	5.5		
Induration: Moderate (n=267, 274)	0.7	2.6		
Induration: Severe (n=266, 273)	0	0		
Erythema: Any (n=270, 275)	11.1	14.5		
Erythema: Mild (n=270, 275)	10.7	14.2		
Erythema: Moderate (n=266, 273)	0.4	0.7		
Erythema: Severe (n=266, 273)	0	0		

Notes:

[32] - N=number of subjects reporting any local reactions.

[33] - N=number of subjects reporting any local reactions

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Infant Series Dose 2 (4 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Infant Series Dose 2 (4 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 cm to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population. (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (4 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	271[34]	268[35]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=264, 266)	37.5	32.7		
Tenderness: Significant (n=248, 252)	3.6	3.6		
Induration: Any (n=251, 253)	10.8	11.5		
Induration: Mild (n=251, 253)	10.4	11.5		
Induration: Moderate (n=245, 252)	0.8	0.4		
Induration: Severe (n=245, 252)	0	0		
Erythema: Any (n=258, 257)	18.2	18.3		
Erythema: Mild (n=256, 257)	16.8	17.9		
Erythema: Moderate (n=247, 252)	2	0.8		
Erythema: Severe (n=245, 252)	0	0		

Notes:

[34] - N=number of subjects reporting any local reactions.

[35] - N=number of subjects reporting any local reactions.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Infant Series Dose 3 (6 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Infant Series Dose 3 (6 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 cm to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population; (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (6 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	251[36]	264[37]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=245, 257)	27.3	28		
Tenderness: Significant (n=238, 244)	3.8	0.8		
Induration: Any (n=243, 250)	11.5	10		
Induration: Mild (n=243, 250)	11.1	9.6		
Induration: Moderate (n=238, 244)	0.8	1.2		
Induration: Severe (n=237, 244)	0	0		

Erythema: Any (n=244, 253)	16.4	17.8		
Erythema: Mild (n=244, 253)	16.4	17		
Erythema: Moderate (n=237, 244)	0.4	0.8		
Erythema: Severe (n=237, 244)	0	0		

Notes:

[36] - N=number of subjects reporting any local reactions.

[37] - N=number of subjects reporting any local reactions.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Toddler Dose (12 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions in the 13vPnC and 7vPnC Groups: Toddler Dose (12 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 cm to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population; (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (12 months of age)

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223[38]	227[39]		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=216, 223)	25	28.7		
Tenderness: Significant (n=198, 210)	2.5	1		
Induration: Any (n=198, 213)	11.1	9.4		
Induration: Mild (n=198, 213)	10.6	8.9		
Induration: Moderate (n=196, 210)	1	2.4		
Induration: Severe (n=195, 210)	0	0		
Erythema: Any (n=204, 216)	19.6	16.7		
Erythema: Mild (n=202, 216)	18.8	14.8		
Erythema: Moderate (n=197, 210)	2.5	2.4		
Erythema: Severe (n=195, 210)	0	0		

Notes:

[38] - N=number of subjects reporting any local reactions.

[39] - N=number of subjects reporting any local reactions.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Infant Series Dose 1 (2 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Infant Series Dose 1 (2 Months of Age)

End point description:

Systemic events (any fever ≥38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population; (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (2 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296[40]	298[41]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C (n=269, 273)	8.9	9.2		
Fever >39 but ≤40 degrees C (n=267, 273)	0.7	0		
Fever >40 degrees C (n=266, 273)	0	0		
Decreased appetite (n=279, 283)	42.7	36		
Irritability (n=291, 288)	80.8	83		
Increased sleep (n=286, 292)	62.9	64.7		
Decreased sleep (n=276, 276)	29.7	28.3		

Notes:

[40] - Subjects reporting any systemic events.

[41] - Subjects reporting any systemic events.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Infant Series Dose 2 (4 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Infant Series Dose 2 (4 Months of Age)

End point description:

Systemic events (any fever ≥38 degrees C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population; (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (4 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	288[42]	290[43]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C (n=249, 255)	8	7.5		
Fever >39 but ≤40 degrees C (n=245, 253)	0.4	0.4		
Fever >40 degrees C (n=245, 252)	0	0		
Decreased appetite (n=254, 262)	28.7	31.3		
Irritability (n=283, 281)	71	70.1		
Increased sleep (n=263, 275)	54.4	52.4		
Decreased sleep (n=256, 261)	25.8	31		

Notes:

[42] - Subjects reporting any systemic events.

[43] - Subjects reporting any systemic events.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Infant Series Dose 3 (6 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Infant Series Dose 3 (6 Months of Age)

End point description:

Systemic events (any fever ≥38 degrees C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population; (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (6 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	275[44]	277[45]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C (n=237, 244)	8.9	5.7		
Fever >39 but ≤40 degrees C (n=237, 244)	0.4	0.8		
Fever >40 degrees C (n=237, 244)	0	0		
Decreased appetite (n=249, 253)	33.3	31.2		

Irritability (n=266, 270)	68	65.9		
Increased sleep (n=255, 258)	35.7	39.9		
Decreased sleep (n=251, 254)	29.9	28.3		

Notes:

[44] - Subjects reporting any systemic events.

[45] - Subjects reporting any systemic events.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Toddler Dose (12 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events in the 13vPnC and 7vPnC Group: Toddler Dose (12 Months of Age)

End point description:

Systemic events (any fever ≥38 degrees Celsius C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population; (n)=number of subjects reporting yes for at least 1 day or no for all days for the 13vPnC and 7vPnC groups, respectively

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose (12 months of age)

End point values	13vPnC Toddler Dose	7vPnC Toddler Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	247[46]	252[47]		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 but ≤39 degrees C (n=203, 213)	13.3	12.2		
Fever >39 but ≤40 degrees C (n=196, 210)	2	1.4		
Fever >40 degrees C (n=195, 210)	0	0.5		
Decreased appetite (n=211, 225)	37	34.2		
Irritability (n=240, 241)	68.8	58.5		
Increased sleep (n=212, 226)	33.5	33.2		
Decreased sleep (n=212, 227)	34	33.9		

Notes:

[46] - Subjects reporting any systemic events.

[47] - Subjects reporting any systemic events.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

AEs: from signing of ICF to 1 month after infant series,and from toddler dose to 1 month after toddler dose. SAEs: from signing of ICF to 6 months after the last study vaccination. Local reactions,systemic events assessed within 4 days of each vaccination

Adverse event reporting additional description:

Safety population was analysed. Adverse Event(AE) term may be reported as both serious,non-serious AE, but are distinct events.AE may = serious for 1 subject and = non-serious for another or subject may have experienced both serious,non-serious episode of the same event. MedDRA version was not captured,here 0.0 is mentioned for dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC Infant Series

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC at 2, 4, and 6 months of age (infant series), co-administered with Pentacel at 2, 4, and 6 months of age; NeisVac-C at 2 and 6 months of age (infant series).

Other Adverse Events (non-serious events): the number affected (N) for nonsystematic (unsolicited) Other Adverse Events N=229; systematic (solicited) Any Local Reactions N=144; systematic (solicited) Any Systemic Events N=273.

Reporting group title	7vPnC Infant Series

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC at 2, 4, and 6 months of age (infant series), co-administered with Pentacel at 2, 4, and 6 months of age; NeisVac-C at 2 and 6 months of age (infant series).

Other Adverse Events (non-serious events): the number affected (N) for nonsystematic (unsolicited) Other Adverse Events N=230; systematic (solicited) Any Local Reactions N=148; systematic (solicited) Any Systemic Events N=279.

Reporting group title	13vPnC After the Infant Series

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC at 2, 4, and 6 months of age (infant series), co-administered with Pentacel at 2, 4, and 6 months of age; NeisVac-C at 2 and 6 months of age (infant series).

Reporting group title	7vPnC After the Infant Series

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC at 2, 4, and 6 months of age (infant series), co-administered with Pentacel at 2, 4, and 6 months of age; NeisVac-C at 2 and 6 months of age (infant series).

Reporting group title	13vPnC Toddler Dose

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC at 12 months of age (toddler dose), co-administered NeisVac-C at 12 months of age (toddler dose); a single type of commercially available MMR at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.

Other Adverse Events (non-serious events): the number affected (N) for nonsystematic (unsolicited) Other Adverse Events N=110; systematic (solicited) Any Local Reactions N=84; systematic (solicited) Any Systemic Events N=199.

Reporting group title	7vPnC Toddler Dose

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC at 12 months of age (toddler dose), co-administered with NeisVac-C at 12 months of age (toddler dose); a single type of commercially available MMR at 12

months; and a single type of commercially available varicella vaccine at 12 months of age.

Other Adverse Events (non-serious events): the number affected (N) for nonsystematic (unsolicited) Other Adverse Events N=108; systematic (solicited) Any Local Reactions N=86; systematic (solicited) Any Systemic Events N=193.

Reporting group title	13vPnC Toddler Dose 6-Month Follow-up

Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC at 12 months of age (toddler dose), co-administered NeisVac-C at 12 months of age (toddler dose); a single type of commercially available MMR at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.

Reporting group title	7vPnC Toddler Dose 6-Month Follow-up

Reporting group description:

Subjects received 1 single 0.5 mL dose of 7vPnC at 12 months of age (toddler dose), co-administered with NeisVac-C at 12 months of age (toddler dose); a single type of commercially available MMR at 12 months; and a single type of commercially available varicella vaccine at 12 months of age.

Serious adverse events	13vPnC Infant Series	7vPnC Infant Series	13vPnC After the Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 300 (1.67%)	5 / 303 (1.65%)	11 / 299 (3.68%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Physical testicle examination abnormal			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (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
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Nervous system disorders			
Febrile convulsion			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Complex partial seizures			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Convulsion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Lymphadenitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
General disorders and administration site conditions			
Developmental delay			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Pyrexia			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	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

Eye swelling			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Bronchospasm			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	4 / 300 (1.33%)	3 / 303 (0.99%)	2 / 299 (0.67%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Gastroenteritis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (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
Mastoiditis			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Meningitis meningococcal			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Pneumonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (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
Viral infection			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (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
Otitis media acute			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Urinary tract infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Influenza			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (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

Serious adverse events	7vPnC After the Infant Series	13vPnC Toddler Dose	7vPnC Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 301 (2.33%)	2 / 286 (0.70%)	2 / 280 (0.71%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Physical testicle examination abnormal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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			
Hydrocele			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (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
Complex partial seizures			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (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
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (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
Lymphadenitis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Developmental delay			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (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
Pyrexia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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

Eye swelling			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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			
Vomiting			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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
Bronchospasm			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 301 (0.66%)	0 / 286 (0.00%)	0 / 280 (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
Croup infectious			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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
Mastoiditis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis meningococcal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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
Influenza			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (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 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Toddler Dose 6-Month Follow-up	7vPnC Toddler Dose 6-Month Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 299 (2.34%)	3 / 301 (1.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Investigations			
Physical testicle examination abnormal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (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			
Hydrocele			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (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 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex partial seizures			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Developmental delay			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye swelling			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 299 (0.00%)	1 / 301 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	3 / 299 (1.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			
subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Mastoiditis			
subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis meningococcal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (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	2 / 299 (0.67%)	3 / 301 (1.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (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 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (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 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	13vPnC Infant Series	7vPnC Infant Series	13vPnC After the Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	273 / 300 (91.00%)	279 / 303 (92.08%)	20 / 299 (6.69%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
Perineal laceration			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Feeling abnormal			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Feeling hot			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			
subjects affected / exposed	4 / 300 (1.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	4	1	0
Injection site erythema			
subjects affected / exposed	15 / 300 (5.00%)	14 / 303 (4.62%)	0 / 299 (0.00%)
occurrences (all)	19	21	0
Injection site haemorrhage			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Injection site induration			
subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	3	0	0
Injection site mass			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	2 / 300 (0.67%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	2	3	0
Injection site reaction			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Injection site swelling			
subjects affected / exposed	4 / 300 (1.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	5	1	0
Irritability			
subjects affected / exposed	18 / 300 (6.00%)	12 / 303 (3.96%)	0 / 299 (0.00%)
occurrences (all)	23	14	0
Malaise			
subjects affected / exposed	0 / 300 (0.00%)	3 / 303 (0.99%)	0 / 299 (0.00%)
occurrences (all)	0	3	0
Oedema peripheral			

subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Peripheral coldness			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	33 / 300 (11.00%)	43 / 303 (14.19%)	0 / 299 (0.00%)
occurrences (all)	37	55	0
Tenderness			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Fever ≥38 degrees Celsius (C) but ≤39 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish 1 occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	24 / 269 (8.92%)	25 / 273 (9.16%)	0 / 299 (0.00%)
occurrences (all)	24	25	0
Fever ≥38 degrees Celsius C but ≤39 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	20 / 249 (8.03%)	19 / 255 (7.45%)	0 / 299 (0.00%)
occurrences (all)	20	19	0
Fever ≥38 degrees Celsius C but ≤39 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	21 / 237 (8.86%)	14 / 244 (5.74%)	0 / 299 (0.00%)
occurrences (all)	21	14	0
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[4]	2 / 267 (0.75%)	0 / 273 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	1 / 245 (0.41%)	1 / 253 (0.40%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	1 / 237 (0.42%)	2 / 244 (0.82%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Fever >40 degrees C: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 266 (0.00%)	0 / 273 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	119 / 279 (42.65%)	102 / 283 (36.04%)	0 / 299 (0.00%)
occurrences (all)	119	102	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	73 / 254 (28.74%)	82 / 262 (31.30%)	0 / 299 (0.00%)
occurrences (all)	73	82	0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	83 / 249 (33.33%) 83	79 / 253 (31.23%) 79	0 / 299 (0.00%) 0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	235 / 291 (80.76%) 235	239 / 288 (82.99%) 239	0 / 299 (0.00%) 0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	201 / 283 (71.02%) 201	197 / 281 (70.11%) 197	0 / 299 (0.00%) 0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	181 / 266 (68.05%) 181	178 / 270 (65.93%) 178	0 / 299 (0.00%) 0
Increased sleep: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	180 / 286 (62.94%) 180	189 / 292 (64.73%) 189	0 / 299 (0.00%) 0
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[15]	143 / 263 (54.37%)	144 / 275 (52.36%)	0 / 299 (0.00%)
occurrences (all)	143	144	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	91 / 255 (35.69%)	103 / 258 (39.92%)	0 / 299 (0.00%)
occurrences (all)	91	103	0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	82 / 276 (29.71%)	78 / 276 (28.26%)	0 / 299 (0.00%)
occurrences (all)	82	78	0
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	66 / 256 (25.78%)	81 / 261 (31.03%)	0 / 299 (0.00%)
occurrences (all)	66	81	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	75 / 251 (29.88%)	72 / 254 (28.35%)	0 / 299 (0.00%)
occurrences (all)	75	72	0
Immune system disorders			
Allergy to metals			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Food allergy			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	3 / 299 (1.00%)
occurrences (all)	1	0	3
Milk allergy			

subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	1 / 299 (0.33%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Genital rash			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Vulval disorder			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 300 (0.00%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	0	2	0
Cough			
subjects affected / exposed	29 / 300 (9.67%)	22 / 303 (7.26%)	1 / 299 (0.33%)
occurrences (all)	36	28	1
Dysphonia			
subjects affected / exposed	2 / 300 (0.67%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Nasal congestion			
subjects affected / exposed	31 / 300 (10.33%)	21 / 303 (6.93%)	1 / 299 (0.33%)
occurrences (all)	40	24	1
Oropharyngeal pain			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	1 / 300 (0.33%)	3 / 303 (0.99%)	0 / 299 (0.00%)
occurrences (all)	1	3	0
Pharyngeal ulceration			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Respiratory disorder			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	23 / 300 (7.67%)	20 / 303 (6.60%)	0 / 299 (0.00%)
occurrences (all)	28	20	0
Sneezing			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 300 (0.00%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	0	2	0
Wheezing			
subjects affected / exposed	3 / 300 (1.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Crying			
subjects affected / exposed	2 / 300 (0.67%)	5 / 303 (1.65%)	0 / 299 (0.00%)
occurrences (all)	3	7	0
Insomnia			
subjects affected / exposed	1 / 300 (0.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Listless			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0

Tearfulness			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Investigations			
Cardiac murmur			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Physical examination abnormal			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Accidental needle stick			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Head injury			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Dacryostenosis congenital			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Hydrocele			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0

Plagiocephaly			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Ventricular septal defect			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Ankyloglossia congenital			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Head titubation			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Hypersomnia			
subjects affected / exposed	1 / 300 (0.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Lethargy			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Poor quality sleep			
subjects affected / exposed	2 / 300 (0.67%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	2	2	0
Psychomotor hyperactivity			

subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Somnolence			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Tremor			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Dyskinesia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	1 / 299 (0.33%)
occurrences (all)	0	0	2
Movement disorder			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	5 / 300 (1.67%)	9 / 303 (2.97%)	0 / 299 (0.00%)
occurrences (all)	5	10	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 300 (0.00%)	3 / 303 (0.99%)	0 / 299 (0.00%)
occurrences (all)	0	3	0
Eye discharge			
subjects affected / exposed	7 / 300 (2.33%)	4 / 303 (1.32%)	0 / 299 (0.00%)
occurrences (all)	8	5	0
Eye oedema			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Hypermetropia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 300 (1.00%)	6 / 303 (1.98%)	0 / 299 (0.00%)
occurrences (all)	4	6	0
Constipation			
subjects affected / exposed	13 / 300 (4.33%)	3 / 303 (0.99%)	3 / 299 (1.00%)
occurrences (all)	15	3	3
Dental discomfort			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	30 / 300 (10.00%)	29 / 303 (9.57%)	1 / 299 (0.33%)
occurrences (all)	35	32	1
Faecal volume increased			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Faeces discoloured			
subjects affected / exposed	0 / 300 (0.00%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	4 / 300 (1.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	4	2	0
Frequent bowel movements			
subjects affected / exposed	2 / 300 (0.67%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	2	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 300 (2.00%)	7 / 303 (2.31%)	0 / 299 (0.00%)
occurrences (all)	7	8	0

Gingival cyst			
subjects affected / exposed	0 / 300 (0.00%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	0	2	0
Gingival pain			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	3	0
Infantile spitting up			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Melaena			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Regurgitation			
subjects affected / exposed	2 / 300 (0.67%)	7 / 303 (2.31%)	0 / 299 (0.00%)
occurrences (all)	3	13	0
Teething			
subjects affected / exposed	16 / 300 (5.33%)	14 / 303 (4.62%)	0 / 299 (0.00%)
occurrences (all)	21	17	0
Umbilical hernia			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Vomiting			
subjects affected / exposed	22 / 300 (7.33%)	19 / 303 (6.27%)	0 / 299 (0.00%)
occurrences (all)	24	23	0
Vomiting neonatal			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Vomiting projectile			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	3	0
Blister			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Dandruff			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	2 / 300 (0.67%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	2	1	0
Dermatitis atopic			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	12 / 300 (4.00%)	7 / 303 (2.31%)	1 / 299 (0.33%)
occurrences (all)	16	8	1
Drug eruption			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	3 / 300 (1.00%)	2 / 303 (0.66%)	1 / 299 (0.33%)
occurrences (all)	3	2	1
Eczema			
subjects affected / exposed	19 / 300 (6.33%)	24 / 303 (7.92%)	1 / 299 (0.33%)
occurrences (all)	21	26	1
Erythema			

subjects affected / exposed	1 / 300 (0.33%)	5 / 303 (1.65%)	0 / 299 (0.00%)
occurrences (all)	1	5	0
Erythema multiforme			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Pustular psoriasis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	14 / 300 (4.67%)	19 / 303 (6.27%)	0 / 299 (0.00%)
occurrences (all)	14	21	0
Rash erythematous			
subjects affected / exposed	1 / 300 (0.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Rash generalised			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Seborrhoea			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Skin discoloration			

subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Skin nodule			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Skin plaque			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Skin warm			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	4 / 300 (1.33%)	3 / 303 (0.99%)	1 / 299 (0.33%)
occurrences (all)	4	3	1
Xeroderma			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Livedo reticularis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	1 / 299 (0.33%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	1 / 299 (0.33%)
occurrences (all)	0	0	1
Tenderness (any): Infant Series	Additional description: Subjects affected and occurrences for LRs, SEs is same		

Dose 1 and Toddler Dose	as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	125 / 281 (44.48%)	124 / 283 (43.82%)	0 / 299 (0.00%)
occurrences (all)	125	124	0
Tenderness (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	99 / 264 (37.50%)	87 / 266 (32.71%)	0 / 299 (0.00%)
occurrences (all)	99	87	0
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	67 / 245 (27.35%)	72 / 257 (28.02%)	0 / 299 (0.00%)
occurrences (all)	67	72	0
Tenderness(significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Tenderness (significant) =present and interfered with limb movement.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	12 / 270 (4.44%)	11 / 274 (4.01%)	0 / 299 (0.00%)
occurrences (all)	12	11	0
Tenderness(significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	9 / 248 (3.63%)	9 / 252 (3.57%)	0 / 299 (0.00%)
occurrences (all)	9	9	0
Tenderness(significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[25]	9 / 238 (3.78%)	2 / 244 (0.82%)	0 / 299 (0.00%)
occurrences (all)	9	2	0
Induration (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (any)=present at site of vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	16 / 271 (5.90%)	20 / 276 (7.25%)	0 / 299 (0.00%)
occurrences (all)	16	20	0
Induration (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	27 / 251 (10.76%)	29 / 253 (11.46%)	0 / 299 (0.00%)
occurrences (all)	27	29	0
Induration (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	28 / 243 (11.52%)	25 / 250 (10.00%)	0 / 299 (0.00%)
occurrences (all)	28	25	0
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (mild)=0.5 centimeters (cm) to 2.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	15 / 270 (5.56%)	15 / 275 (5.45%)	0 / 299 (0.00%)
occurrences (all)	15	15	0
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	26 / 251 (10.36%)	29 / 253 (11.46%)	0 / 299 (0.00%)
occurrences (all)	26	29	0
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		

alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	27 / 243 (11.11%)	24 / 250 (9.60%)	0 / 299 (0.00%)
occurrences (all)	27	24	0
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (moderate)=2.5 cm to 7.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	2 / 267 (0.75%)	7 / 274 (2.55%)	0 / 299 (0.00%)
occurrences (all)	2	7	0
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	2 / 245 (0.82%)	1 / 252 (0.40%)	0 / 299 (0.00%)
occurrences (all)	2	1	0
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	2 / 238 (0.84%)	3 / 244 (1.23%)	0 / 299 (0.00%)
occurrences (all)	2	3	0
Erythema (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (any)=present at site of vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	30 / 270 (11.11%)	40 / 275 (14.55%)	0 / 299 (0.00%)
occurrences (all)	30	40	0
Erythema (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[36]	47 / 258 (18.22%)	47 / 257 (18.29%)	0 / 299 (0.00%)
occurrences (all)	47	47	0
Erythema (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (mild)=0.5 cm to 2.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	29 / 270 (10.74%)	39 / 275 (14.18%)	0 / 299 (0.00%)
occurrences (all)	29	39	0
Erythema (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	43 / 256 (16.80%)	46 / 257 (17.90%)	0 / 299 (0.00%)
occurrences (all)	43	46	0
Erythema (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	40 / 244 (16.39%)	43 / 253 (17.00%)	0 / 299 (0.00%)
occurrences (all)	40	43	0
Erythema (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (moderate)=2.5 cm to 7.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	1 / 266 (0.38%)	2 / 273 (0.73%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Erythema (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	5 / 247 (2.02%)	2 / 252 (0.79%)	0 / 299 (0.00%)
occurrences (all)	5	2	0
Erythema (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	1 / 237 (0.42%) 1	2 / 244 (0.82%) 2	0 / 299 (0.00%) 0
Erythema (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[43] occurrences (all)	40 / 244 (16.39%) 40	45 / 253 (17.79%) 45	0 / 299 (0.00%) 0
Renal and urinary disorders			
Chromaturia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 303 (0.00%) 0	0 / 299 (0.00%) 0
Hydronephrosis subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 303 (0.00%) 0	0 / 299 (0.00%) 0
Renal cyst subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 303 (0.00%) 0	0 / 299 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Muscle spasms subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 303 (0.00%) 0	0 / 299 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	1 / 303 (0.33%) 1	0 / 299 (0.00%) 0
Torticollis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	2 / 303 (0.66%) 2	0 / 299 (0.00%) 0
Positional plagiocephaly subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 303 (0.00%) 0	0 / 299 (0.00%) 0
Infections and infestations			

Acarodermatitis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	12 / 300 (4.00%)	11 / 303 (3.63%)	0 / 299 (0.00%)
occurrences (all)	12	12	0
Bronchitis			
subjects affected / exposed	2 / 300 (0.67%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	2	2	0
Candida nappy rash			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Candidiasis			
subjects affected / exposed	3 / 300 (1.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	3	1	0
Cellulitis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis infective			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Croup infectious			
subjects affected / exposed	5 / 300 (1.67%)	4 / 303 (1.32%)	0 / 299 (0.00%)
occurrences (all)	5	4	0
Cystitis			
subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Ear infection			
subjects affected / exposed	8 / 300 (2.67%)	10 / 303 (3.30%)	0 / 299 (0.00%)
occurrences (all)	10	10	0
Eye infection			
subjects affected / exposed	4 / 300 (1.33%)	5 / 303 (1.65%)	0 / 299 (0.00%)
occurrences (all)	4	5	0
Gastroenteritis			
subjects affected / exposed	13 / 300 (4.33%)	12 / 303 (3.96%)	0 / 299 (0.00%)
occurrences (all)	14	12	0

Gastroenteritis viral			
subjects affected / exposed	5 / 300 (1.67%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	6	2	0
Fungal infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 300 (0.33%)	3 / 303 (0.99%)	0 / 299 (0.00%)
occurrences (all)	1	3	0
Incision site infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	2 / 300 (0.67%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	2	2	0
Localised infection			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	3 / 300 (1.00%)	3 / 303 (0.99%)	0 / 299 (0.00%)
occurrences (all)	3	3	0
Nasopharyngitis			
subjects affected / exposed	68 / 300 (22.67%)	60 / 303 (19.80%)	0 / 299 (0.00%)
occurrences (all)	90	78	0
Oral candidiasis			
subjects affected / exposed	7 / 300 (2.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	8	3	0
Otitis media			
subjects affected / exposed	5 / 300 (1.67%)	9 / 303 (2.97%)	0 / 299 (0.00%)
occurrences (all)	5	11	0
Otitis media acute			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0

Paronychia			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 300 (0.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Roseola			
subjects affected / exposed	3 / 300 (1.00%)	5 / 303 (1.65%)	0 / 299 (0.00%)
occurrences (all)	3	5	0
Sinusitis			
subjects affected / exposed	1 / 300 (0.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Skin candida			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0

Upper respiratory tract infection			
subjects affected / exposed	60 / 300 (20.00%)	53 / 303 (17.49%)	4 / 299 (1.34%)
occurrences (all)	82	77	4
Varicella			
subjects affected / exposed	1 / 300 (0.33%)	2 / 303 (0.66%)	0 / 299 (0.00%)
occurrences (all)	1	2	0
Viral infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Viral skin infection			
subjects affected / exposed	2 / 300 (0.67%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	2	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	1	0
Coxsackie viral infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Injection site infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Measles			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Measles post vaccine			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0

Tonsillitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Viraemia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	1 / 299 (0.33%)
occurrences (all)	0	0	1
Otitis media chronic			
subjects affected / exposed	0 / 300 (0.00%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 300 (0.33%)	5 / 303 (1.65%)	0 / 299 (0.00%)
occurrences (all)	1	5	0
Anorexia			
subjects affected / exposed	1 / 300 (0.33%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	1	1	0
Dehydration			
subjects affected / exposed	1 / 300 (0.33%)	0 / 303 (0.00%)	0 / 299 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	0 / 300 (0.00%)	1 / 303 (0.33%)	0 / 299 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	7vPnC After the Infant Series	13vPnC Toddler Dose	7vPnC Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 301 (5.32%)	199 / 286 (69.58%)	193 / 280 (68.93%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Perineal laceration			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Feeling abnormal			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	1 / 280 (0.36%)
occurrences (all)	0	1	1
Injection site haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Injection site mass			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	4 / 280 (1.43%)
occurrences (all)	0	3	4
Malaise			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 301 (0.00%)	20 / 286 (6.99%)	23 / 280 (8.21%)
occurrences (all)	0	21	27
Tenderness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Fever ≥38 degrees Celsius (C) but ≤39 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish 1 occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 301 (0.00%)	27 / 203 (13.30%)	26 / 213 (12.21%)
occurrences (all)	0	27	26
Fever ≥38 degrees Celsius C but ≤39 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0

Fever ≥38 degrees Celsius C but ≤39 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 301 (0.00%)	4 / 196 (2.04%)	3 / 210 (1.43%)
occurrences (all)	0	4	3
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Fever >40 degrees C: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 301 (0.00%)	0 / 195 (0.00%)	1 / 210 (0.48%)
occurrences (all)	0	0	1
Decreased appetite: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[8]	0 / 301 (0.00%)	78 / 211 (36.97%)	77 / 225 (34.22%)
occurrences (all)	0	78	77
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 301 (0.00%)	165 / 240 (68.75%)	141 / 241 (58.51%)
occurrences (all)	0	165	141
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 301 (0.00%)	71 / 212 (33.49%)	75 / 226 (33.19%)
occurrences (all)	0	71	75
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 301 (0.00%)	72 / 212 (33.96%)	77 / 227 (33.92%)
occurrences (all)	0	72	77
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[19]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to metals			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Food allergy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Genital rash			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	2 / 280 (0.71%)
occurrences (all)	0	0	2
Vulval disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 301 (0.00%)	4 / 286 (1.40%)	6 / 280 (2.14%)
occurrences (all)	0	5	6
Dysphonia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 301 (0.00%)	8 / 286 (2.80%)	3 / 280 (1.07%)
occurrences (all)	0	9	3
Oropharyngeal pain			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Pharyngeal erythema			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Pharyngeal ulceration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 301 (0.33%)	9 / 286 (3.15%)	4 / 280 (1.43%)
occurrences (all)	1	9	4
Sneezing			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0

Crying			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	1 / 280 (0.36%)
occurrences (all)	0	1	1
Listless			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Tearfulness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Physical examination abnormal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental needle stick			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			

Cryptorchism			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis congenital			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Plagiocephaly			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Ventricular septal defect			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Ankyloglossia congenital			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Head titubation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Psychomotor hyperactivity			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Movement disorder			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 301 (0.00%)	3 / 286 (1.05%)	3 / 280 (1.07%)
occurrences (all)	0	3	3
Dacryostenosis acquired			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Eye oedema			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Hypermetropia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Dental discomfort			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 301 (0.00%)	6 / 286 (2.10%)	5 / 280 (1.79%)
occurrences (all)	0	6	5
Faecal volume increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Gingival cyst			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Infantile spitting up			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	1 / 280 (0.36%)
occurrences (all)	0	2	2
Umbilical hernia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 301 (0.00%)	8 / 286 (2.80%)	5 / 280 (1.79%)
occurrences (all)	0	8	5

Vomiting neonatal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Vomiting projectile			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Blister			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Cold sweat			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dandruff			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	1 / 280 (0.36%)
occurrences (all)	0	1	1
Dermatitis diaper			
subjects affected / exposed	0 / 301 (0.00%)	3 / 286 (1.05%)	2 / 280 (0.71%)
occurrences (all)	0	3	2
Drug eruption			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 301 (0.00%)	3 / 286 (1.05%)	0 / 280 (0.00%)
occurrences (all)	0	3	0
Erythema			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Heat rash			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Pustular psoriasis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 301 (0.33%)	17 / 286 (5.94%)	19 / 280 (6.79%)
occurrences (all)	1	17	23
Rash erythematous			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	2 / 280 (0.71%)
occurrences (all)	0	1	2
Rash generalised			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	1 / 280 (0.36%)
occurrences (all)	0	1	1
Rash papular			

subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Seborrhoea			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin discoloration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Skin irritation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin nodule			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin warm			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Xeroderma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			

subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 301 (0.00%)	54 / 216 (25.00%)	64 / 223 (28.70%)
occurrences (all)	0	54	64
Tenderness (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Tenderness(significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Tenderness (significant) =present and interfered with limb movement.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 301 (0.00%)	5 / 198 (2.53%)	2 / 210 (0.95%)
occurrences (all)	0	5	2
Tenderness(significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local			

Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Tenderness(significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Induration (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (any)=present at site of vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 301 (0.00%)	22 / 198 (11.11%)	20 / 213 (9.39%)
occurrences (all)	0	22	20
Induration (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Induration (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (mild)=0.5 centimeters (cm) to 2.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[29]	0 / 301 (0.00%)	21 / 198 (10.61%)	19 / 213 (8.92%)
occurrences (all)	0	21	19
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (moderate)=2.5 cm to 7.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 301 (0.00%)	2 / 196 (1.02%)	5 / 210 (2.38%)
occurrences (all)	0	2	5
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Erythema (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (any)=present at site of vaccination.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[35] occurrences (all)	0 / 301 (0.00%) 0	40 / 204 (19.61%) 40	36 / 216 (16.67%) 36
Erythema (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[36] occurrences (all)	0 / 301 (0.00%) 0	0 / 286 (0.00%) 0	0 / 280 (0.00%) 0
Erythema (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (mild)=0.5 cm to 2.0 cm.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	0 / 301 (0.00%) 0	38 / 202 (18.81%) 38	32 / 216 (14.81%) 32
Erythema (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	0 / 301 (0.00%) 0	0 / 286 (0.00%) 0	0 / 280 (0.00%) 0
Erythema (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	0 / 301 (0.00%) 0	0 / 286 (0.00%) 0	0 / 280 (0.00%) 0
Erythema (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (moderate)=2.5 cm to 7.0 cm.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[40]	0 / 301 (0.00%)	5 / 197 (2.54%)	5 / 210 (2.38%)
occurrences (all)	0	5	5
Erythema (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Erythema (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Erythema (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0

Pain in extremity			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Torticollis			
subjects affected / exposed	2 / 301 (0.66%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	2	0	0
Positional plagiocephaly			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 301 (0.00%)	3 / 286 (1.05%)	3 / 280 (1.07%)
occurrences (all)	0	3	3
Bronchitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Candida nappy rash			
subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	1 / 280 (0.36%)
occurrences (all)	0	2	1
Candidiasis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Croup infectious			
subjects affected / exposed	1 / 301 (0.33%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	1	1	0
Cystitis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 301 (0.00%)	8 / 286 (2.80%)	3 / 280 (1.07%)
occurrences (all)	0	8	3
Eye infection			
subjects affected / exposed	0 / 301 (0.00%)	3 / 286 (1.05%)	0 / 280 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis			
subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	3 / 280 (1.07%)
occurrences (all)	0	2	3
Gastroenteritis viral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	1 / 280 (0.36%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Incision site infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	1 / 301 (0.33%)	10 / 286 (3.50%)	13 / 280 (4.64%)
occurrences (all)	1	11	14
Oral candidiasis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	1 / 301 (0.33%)	9 / 286 (3.15%)	6 / 280 (2.14%)
occurrences (all)	1	9	6
Otitis media acute			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	1 / 280 (0.36%)
occurrences (all)	0	2	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Roseola			

subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	3 / 280 (1.07%)
occurrences (all)	0	2	3
Sinusitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Skin candida			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 301 (0.33%)	18 / 286 (6.29%)	19 / 280 (6.79%)
occurrences (all)	1	19	19
Varicella			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	1 / 280 (0.36%)
occurrences (all)	0	2	1
Viral skin infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	4 / 280 (1.43%)
occurrences (all)	0	0	4
Gastroenteritis norovirus			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Hand-foot-and-mouth disease			

subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Injection site infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Measles			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Measles post vaccine			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	1 / 280 (0.36%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 301 (0.00%)	2 / 286 (0.70%)	0 / 280 (0.00%)
occurrences (all)	0	2	0
Viraemia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	0 / 280 (0.00%)
occurrences (all)	0	1	0
Molluscum contagiosum			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	1 / 301 (0.33%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 301 (0.00%)	1 / 286 (0.35%)	2 / 280 (0.71%)
occurrences (all)	0	1	2
Anorexia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 301 (0.00%)	0 / 286 (0.00%)	0 / 280 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC Toddler Dose 6-Month Follow-up	7vPnC Toddler Dose 6-Month Follow-up	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 299 (2.01%)	4 / 301 (1.33%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of skin			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pregnancy, puerperium and perinatal conditions			
Perineal laceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Feeling abnormal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Feeling hot			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site bruising			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site erythema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site haemorrhage			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site induration			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site mass			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Peripheral coldness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tenderness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever ≥38 degrees Celsius (C) but ≤39 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish 1 occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever ≥38 degrees Celsius C but ≤39 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever ≥38 degrees Celsius C but ≤39 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever >39 degrees C but ≤40 degrees C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fever >40 degrees C: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence		

	from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Decreased appetite: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[12]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Increased sleep: Infant Series Dose 1 and Toddler dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		

alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Allergy to metals			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Food allergy			
subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences (all)	1	0	
Milk allergy			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Genital rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Vulval disorder			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 299 (0.67%)	1 / 301 (0.33%)	
occurrences (all)	2	1	
Bronchial hyperreactivity			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pharyngeal erythema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pharyngeal ulceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Respiratory disorder			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Sneezing			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract congestion			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Crying			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Listless			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tearfulness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Physical examination abnormal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Accidental needle stick			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Head injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Joint dislocation			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Joint injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dacryostenosis congenital			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Hydrocele			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Plagiocephaly			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Ventricular septal defect			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Ankyloglossia congenital			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences (all)	1	0	
Headache			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Head titubation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Hyperaesthesia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Hypersomnia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Lethargy			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Poor quality sleep			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Psychomotor hyperactivity			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dyskinesia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Movement disorder			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dacryostenosis acquired			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Eye discharge			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Eye oedema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Lacrimation increased			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Hypermetropia			
subjects affected / exposed	1 / 299 (0.33%)	1 / 301 (0.33%)	
occurrences (all)	1	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 299 (0.00%)	1 / 301 (0.33%)	
occurrences (all)	0	1	
Dental discomfort			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			

subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences (all)	1	0	
Faecal volume increased			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Faeces discoloured			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Frequent bowel movements			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Gingival cyst			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Gingival pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Infantile spitting up			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Melaena			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Regurgitation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Teething			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Umbilical hernia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	1 / 299 (0.33%)	0 / 301 (0.00%)	
occurrences (all)	1	0	
Vomiting neonatal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Vomiting projectile			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Blister			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Cold sweat			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dandruff			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	

Dermatitis contact			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dermatitis diaper			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Drug eruption			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema multiforme			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Heat rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pustular psoriasis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Rash erythematous			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	

Rash generalised			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Rash macular			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Rash papular			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Seborrhoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin discoloration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin irritation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin nodule			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin plaque			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin warm			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Swelling face			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	

Urticaria			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Xeroderma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Livedo reticularis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Psoriasis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin lesion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tenderness (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tenderness (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tenderness(significant): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Tenderness (significant) =present and interfered with limb movement.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Tenderness(significant): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Tenderness(significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Induration (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (any)=present at site of vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[26] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Induration (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Induration (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[28] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	

Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (mild)=0.5 centimeters (cm) to 2.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Induration (moderate)=2.5 cm to 7.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[34]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (any)=present at site of vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (mild)=0.5 cm to 2.0 cm.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Erythema (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Erythema (moderate)=2.5 cm to 7.0 cm.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[40] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Erythema (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[41] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Erythema (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Erythema (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs, SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs, SEs were assessed only for infant series and toddler dose groups.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[43] occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Renal and urinary disorders			
Chromaturia subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Hydronephrosis subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	1 / 301 (0.33%) 1	
Renal cyst subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	
Musculoskeletal and connective tissue disorders			

Muscle spasms			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Torticollis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Positional plagiocephaly			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Bronchiolitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Candida nappy rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Candidiasis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis infective			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Croup infectious			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Eye infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fungal infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Impetigo			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Incision site infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Laryngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Localised infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Otitis media acute			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Rhinitis			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Roseola			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Skin candida			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Staphylococcal skin infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Varicella			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Viral skin infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Coxsackie viral infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis norovirus			

subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Injection site infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Measles			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Measles post vaccine			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Viraemia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Molluscum contagiosum			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Otitis media chronic			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Anorexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 301 (0.00%)	
occurrences (all)	0	0	

Increased appetite subjects affected / exposed occurrences (all)	0 / 299 (0.00%) 0	0 / 301 (0.00%) 0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:

Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[21] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[25] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[26] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[27] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[28] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[29] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[30] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[31] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[32] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[33] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[34] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[35] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[36] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[37] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[38] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[39] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[40] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[41] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[42] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[43] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported