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 the United Kingdom

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

Summary

EudraCT number	2005-005130-12
Trial protocol	GB
Global end of trial date	21 October 2008

Results information

Result version number	v2 (current)
This version publication date	28 July 2016
First version publication date	01 August 2015
Version creation reason	• Correction of full data set Not completed reason having type "Other" with same other reason text

Trial information

Trial identification

Sponsor protocol code	6096A1-007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00384059
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851090

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000036-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 February 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 October 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immune response induced by NeisVac-C (meningococcal group C vaccine) given with 13-valent Pneumococcal Conjugate Vaccine (13vPnC) relative to the immune response induced by NeisVac-C given with 7-valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the infant series. The immune response was assessed using a meningococcal group C-specific serum bactericidal assay (SBA).
To evaluate the immune responses induced by Pediacel given with 13vPnC relative to the immune responses induced by Pediacel given with 7vPnC when measured 1 month after the infant series. The immune responses to the following antigens in Pediacel were assessed: acellular pertussis antigens (pertussis toxoid [PT], filamentous hemagglutinin [FHA], pertactin [PRN], and fimbrial agglutinogens [FIM]) and 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	19 October 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 286
Worldwide total number of subjects	286
EEA total number of subjects	286

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)	286
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 the United Kingdom (UK) from October 2006 to June 2007.

Pre-assignment

Screening details:

Subjects were enrolled into the study according to inclusion/exclusion criteria without a screening period. Out of 286 subjects, demographic has been reported for 278, since demographic information for 8 subjects was unknown, as they were pre-randomized but not consented.

Period 1

Period 1 title	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 Infant Series

Arm description:

Subjects received 13vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and a combined diphtheria, tetanus, five component acellular pertussis (DT5aP), inactivated poliomyelitis (IPV) and Haemophilus influenzae type b (Hib) conjugate vaccine (Pediacel) at the 2- and 4-month visit (infant series). Pediacel was administered without study vaccine at 3 month visit.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of 13vPnC at 2 and 4 month (infant series).

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

Dosage and administration details:

Subjects received one single 0.5-mL dose of Pediacel at the 2, 3 and 4 month (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 one single 0.5-mL dose of NeisVac-C at 2 and 4 months of age (infant series).

Arm title	7vPnC Infant Series

Arm description:

Subjects received 7vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visit

(infant series). Pediacel was administered without study vaccine at 3-month visit.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of 7vPnC at the 2 and 4 month (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 one single 0.5 mL dose of NeisVac-C at 2 and 4 month (infant series).

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of Pediacel at 2, 3 and 4 months (infant series).

Number of subjects in period 1	13vPnC Infant Series	7vPnC Infant Series
Started	141	145
Vaccinated Dose 1	139	139
Vaccinated Dose 2	136	135
Completed	135	132
Not completed	6	13
Consent withdrawn by subject	2	2
Adverse Event	1	2
Protocol Violation	1	2
Not consented	2	6
Lost to follow-up	-	1

Period 2

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

Roles blinded	Subject, Investigator, Carer, Assessor

Arms

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

Arm description:

Included subjects who received 13vPnC coadministered with NeisVac-C vaccine and a combined DT5aP, IPVand Hib conjugate vaccine (Pediacel) at at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	7vPnC After Infant Series

Arm description:

Included subjects who received 7vPnC coadministered with NeisVac-C vaccine and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC After Infant Series	7vPnC After Infant Series
Started	135	132
Completed	131	122
Not completed	4	10
Consent withdrawn by subject	2	2
Physician decision	-	1
Failed to return	-	2
Adverse Event	-	1
Protocol Violation	2	3
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	Investigator, Subject, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes

Arm title	13vPnC Toddler Dose
Arm description:	
Subjects recieved 13vPnC coadministered with Hib and Meningococcal C Vaccine (Menitorix) at the 12-month visit (toddler dose).	
Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received one single 0.5 mL dose of 13vPnC at 12-month visit (toddler dose).	
Investigational medicinal product name	Menitorix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received one single 0.5 mL dose of Menitorix at the 12-month visit (toddler dose).	
Arm title	7vPnC Toddler Dose
Arm description:	
Subjects received 7vPnC coadministered with Hib and Meningococcal C Vaccine (Menitorix) at the 12-month visit (toddler dose).	
Arm type	Active comparator
Investigational medicinal product name	Menitorix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received one single 0.5 mL dose of Menitorix at the 12-month visit (toddler dose).	
Investigational medicinal product name	7vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects recieved one single 0.5 mL dose of 7vPnC at the 12-month visit (toddler dose).	

Number of subjects in period 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	131	122
Completed	130	120
Not completed	1	2
Failed to return	-	1
Lost to follow-up	1	1

Period 4

Period 4 title	Baseline Period
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC

Arm description:

Subjects received 13vPnC coadministered with NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of 13vPnC at 2 and 4 month (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 one single 0.5-mL dose of NeisVac-C at 2 and 4 months of age (infant series).

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

Dosage and administration details:

Subjects received one single 0.5-mL dose of Pediacel at the 2, 3 and 4 month (infant series).

Arm title	7vPnC

Arm description:

Subjects received 7vPnC coadministered with NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.

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

Dosage and administration details:

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

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

Dosage and administration details:

Subjects received one single 0.5-mL dose of Pediacel at the 2, 3 and 4 month (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 one single 0.5-mL dose of NeisVac-C at 2 and 4 months of age (infant series).

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification:
The period 1 here does not represent the baseline period however period 4 is the baseline period as the baseline population is based on the evaluable infant immunogenicity population i.
e., the primary immunogenicity analysis population.

Number of subjects in period 4[2][3]	13vPnC	7vPnC
Started	120	118
Completed	120	118

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification:
The number of subjects reported in baseline period are not same as worldwide number because baseline period is based on the evaluable infant immunogenicity population i.
e., the primary immunogenicity analysis population.

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Period 4 has been created to present the Baseline period and includes the data for evaluab le infant immunogenicity population.

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC
Reporting group description:	
Subjects received 13vPnC coadministered with NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.	
Reporting group title	7vPnC
Reporting group description:	
Subjects received 7vPnC coadministered with NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.	

Reporting group values	13vPnC	7vPnC	Total
Number of subjects	120	118	238
Age categorical			
Units: Subjects			
Age continuous			
Units: months			
arithmetic mean	2.1	2.1	
standard deviation	± 0.3	± 0.2	-
Gender categorical			
Units: Subjects			
Female	55	57	112
Male	65	61	126

End points

End points reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description:	
Subjects received 13vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine (NeisVac-C) and a combined diphtheria, tetanus, five component acellular pertussis (DT5aP), inactivated poliomyelitis (IPV) and Haemophilus influenzae type b (Hib) conjugate vaccine (Pediacel) at the 2- and 4-month visit (infant series). Pediacel was administered without study vaccine at 3 month visit.	
Reporting group title	7vPnC Infant Series
Reporting group description:	
Subjects received 7vPnC coadministered with meningococcal C-tetanus toxoid conjugate vaccine NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visit (infant series). Pediacel was administered without study vaccine at 3-month visit.	
Reporting group title	13vPnC After Infant Series
Reporting group description:	
Included subjects who received 13vPnC coadministered with NeisVac-C vaccine and a combined DT5aP, IPVand Hib conjugate vaccine (Pediacel) at at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.	
Reporting group title	7vPnC After Infant Series
Reporting group description:	
Included subjects who received 7vPnC coadministered with NeisVac-C vaccine and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.	
Reporting group title	13vPnC Toddler Dose
Reporting group description:	
Subjects recieved 13vPnC coadministered with Hib and Meningococcal C Vaccine (Menitorix) at the 12-month visit (toddler dose).	
Reporting group title	7vPnC Toddler Dose
Reporting group description:	
Subjects received 7vPnC coadministered with Hib and Meningococcal C Vaccine (Menitorix) at the 12-month visit (toddler dose).	
Reporting group title	13vPnC
Reporting group description:	
Subjects received 13vPnC coadministered with NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.	
Reporting group title	7vPnC
Reporting group description:	
Subjects received 7vPnC coadministered with NeisVac-C and a combined DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (infant series). Pediacel was administered without study vaccine at 3-month visit.	
Subject analysis set title	13vPnC After Infant Series Dose 2
Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C at the 2- and 4-month visits, Pediacel at the 2-, 3-, and 4-month visits.	
Subject analysis set title	13vPnC Before Toddler Dose
Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C at the 2- and 4-month visits, Pediacel at the 2-, 3-, and 4-month visits.	
Subject analysis set title	13vPnC After Toddler Dose
Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 13vPnC coadministrated with Menitorix at the 12-month	

visit.

Subject analysis set title	13vPnC Dose 1
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Pediacel at 2 months of age.

Subject analysis set title	7vPnC Dose 1
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Pediacel at 2 months of age.

Subject analysis set title	13vPnC Dose 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and Pediacel at 4 months of age.

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

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with Menitorix at 12 months of age.

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

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with Menitorix at 12 months of age.

Subject analysis set title	7vPnC Dose 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and Pediacel at 4 months of age.

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

Subject analysis set description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C at the 2- and 4-month visits, Pediacel at the 2-, 3-, and 4-month visits.

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

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C at the 2- and 4-month visits, Pediacel at the 2-, 3-, and 4-month visits.

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

Subject analysis set description:

'Subjects received one single 0.5 mL dose of 13vPnC coadministrated with Menitorix at the 12-month visit.

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

Subject analysis set description:

Subjects received one single 0.5 mL dose of 7vPnC coadministrated with Menitorix at the 12-month visit.

Primary: Percentage of Subjects Achieving a Meningococcal C Serum Bactericidal Assay (SBA) Titer >=1:8 and Predefined Antibody Levels for Pertussis and Haemophilus influenzae Type b in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series.

End point title	Percentage of Subjects Achieving a Meningococcal C Serum Bactericidal Assay (SBA) Titer >=1:8 and Predefined Antibody Levels for Pertussis and Haemophilus influenzae Type b in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series.

End point description:

Percentage of subjects achieving a meningococcal C SBA serum antibody titer greater than or equal to (>=) 1:8 and predefined antibody threshold levels with the corresponding 95 percent (%) confidence interval (CI) for concomitant antigens polyribosylribitol phosphate (PRP) in Haemophilus influenzae type b [Hib](>=0.15 microgram per milliliter (mcg/mL) or >=1.0 mcg/mL), pertussis toxoid [PT], filamentous haemagglutinin, pertactin [FHA], and pertactin (PRN) (>=5 enzyme-linked immunosorbent assay (ELISA) Units (EU)/mL) and fimbrial agglutinogens [FIM] (>=2.2/mL) are presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n)= number of subjects with a determinate postinfant series antibody concentration to the given concomitant antigen.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (5 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	118		
Units: Percentage of subjects				
number (confidence interval 95%)				
Meningococcal C >= 1:8 titer (n=120,118)	99.2 (95.4 to 100)	99.2 (95.4 to 100)		
Hib (PRP) >= 0.15 mcg/mL (n=114,102)	96.5 (91.3 to 99)	98 (93.1 to 99.8)		
Hib (PRP) >= 1.0 mcg/mL (n=114,102)	85.1 (77.2 to 91.1)	89.2 (81.5 to 94.5)		
Pertussis PT >= 5 EU/mL (n=119,112)	100 (96.9 to 100)	100 (96.8 to 100)		
Pertussis PT >= 17 EU/mL (n=119,112)	96.6 (91.6 to 99.1)	95.5 (89.9 to 98.5)		
Pertussis FHA >= 5 EU/mL (n=119,113)	100 (96.9 to 100)	100 (96.8 to 100)		
Pertussis FHA >= 7.82 EU/mL (n=119,113)	100 (96.9 to 100)	100 (96.8 to 100)		
Pertussis FHA >= 20 EU/mL (n=119,113)	94.1 (88.3 to 97.6)	95.6 (90 to 98.5)		
Pertussis PRN >= 5 EU/mL (n=119,113)	100 (96.9 to 100)	100 (96.8 to 100)		
Pertussis PRN >= 15 EU/mL (n=119,113)	92.4 (86.1 to 96.5)	95.6 (90 to 98.5)		
Pertussis FIM >= 2.2 EU/mL (n=119,113)	100 (96.9 to 100)	97.3 (92.4 to 99.4)		
Pertussis FIM >= 5 EU/mL (n=119,113)	97.5 (92.8 to 99.5)	96.5 (91.2 to 99)		

Statistical analyses

Statistical analysis title	Analysis for Meningococcal C >=1:8 titer

Statistical analysis description:

For Meningococcal C the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 titer was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	3.9

Notes:

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

Statistical analysis title	Analysis for Hib (PRP) >=0.15 mcg/mL

Statistical analysis description:

For Haemophilus influenzae type b the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.15 mcg/mL threshold was calculated.

Comparison groups	7vPnC Infant Series v 13vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	3.7

Notes:

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

Statistical analysis title	Analysis for Pertussis PT >=5 EU/mL

Statistical analysis description:

For Pertussis PT the difference in percentage between the two groups (13vPnC - 7vPnC) at 5 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series

Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	3.3

Notes:

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

Statistical analysis title	Analysis for Hib (PRP) >=1.0 mcg/mL

Statistical analysis description:

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

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.4
upper limit	5.1

Notes:

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

Statistical analysis title	Analysis for Pertussis PT >=17 EU/mL

Statistical analysis description:

For Pertussis PT the difference in percentage between the two groups (13vPnC - 7vPnC) at 17 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	7.1

Notes:

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

Statistical analysis title	Analysis for Pertussis FHA >=5 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 5 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	3.2

Notes:

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

Statistical analysis title	Analysis for Pertussis FHA >=7.82 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 7.82 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	3.2

Notes:

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

Statistical analysis title	Analysis for Pertussis FHA >=20 EU/mL

Statistical analysis description:

For Pertussis FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 20 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	4.8

Notes:

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

Statistical analysis title	Analysis for Pertussis PRN >= 5 EU/mL

Statistical analysis description:

For Pertussis PRN the difference in percentage between the two groups (13vPnC - 7vPnC) at 5 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	3.2

Notes:

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

Statistical analysis title	Analysis for Pertussis PRN >=15 EU/mL

Statistical analysis description:

For Pertussis PRN the difference in percentage between the two groups (13vPnC - 7vPnC) at 15 EU/mL threshold was calculated.

Comparison groups	7vPnC Infant Series v 13vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Parameter estimate	Difference
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	3.4

Notes:

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

Statistical analysis title	Analysis for Pertussis FIM >=2.2 EU/mL

Statistical analysis description:

For Pertussis FIM the difference in percentage between the two groups (13vPnC - 7vPnC) at 2.2 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	Difference
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	7.6

Notes:

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

Statistical analysis title	Analysis for Pertussis FIM >=5 EU/mL

Statistical analysis description:

For Pertussis FIM the difference in percentage between the two groups (13vPnC - 7vPnC) at 5 EU/mL threshold was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
Parameter estimate	Difference
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	6.5

Notes:

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

Primary: Geometric Mean Titer (GMT) of Meningococcal C Antigen as Measured by SBA in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series

End point title	Geometric Mean Titer (GMT) of Meningococcal C Antigen as Measured by SBA in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series

End point description:

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

End point type	Primary

End point timeframe:

One month after infant series dose 2 (5 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120[13]	118[14]		
Units: titer				
geometric mean (confidence interval 95%)	306.2 (251.21 to 373.22)	345.42 (287.91 to 414.41)		

Notes:

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

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

Statistical analyses

Statistical analysis title	Analysis for Meningococcal C
Statistical analysis description:	
For Meningococcal C the geometric mean concentration (GMC) ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
Parameter estimate	Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.16

Notes:

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

Primary: Geometric Mean Antibody Concentration of Haemophilus Influenzae Type b (Hib) Polyribosylribitol Phosphate (PRP) as Measured by Enzyme-linked Immunosorbent Assay (ELISA) in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series

End point title	Geometric Mean Antibody Concentration of Haemophilus Influenzae Type b (Hib) Polyribosylribitol Phosphate (PRP) as Measured by Enzyme-linked Immunosorbent Assay (ELISA) in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series
End point description:	
Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.	
End point type	Primary
End point timeframe:	
One month after infant series dose 2 (5 months of age)	

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114[16]	102[17]		
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)	3.4 (2.65 to 4.37)	4.44 (3.5 to 5.63)		

Notes:

[16] - N=number of subjects with determinate antibody concentration/titer for specified concomitant antigen
[17] - N=number of subjects with determinate antibody concentration/titer for specified concomitant antigen

Statistical analyses

Statistical analysis title	Analysis of GMC for Hib
Statistical analysis description:	
For Hib the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
Parameter estimate	Ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.08

Notes:

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

Primary: Geometric Mean Antibody Concentration of Pertusis Filamentous Haemagglutinin (FHA), Pertussis Toxoid (PT), Pertactin (PRN), and Fimbrial Agglutinogens (FIM) as Measured by ELISA in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series

End point title	Geometric Mean Antibody Concentration of Pertusis Filamentous Haemagglutinin (FHA), Pertussis Toxoid (PT), Pertactin (PRN), and Fimbrial Agglutinogens (FIM) as Measured by ELISA in 13vPnC Group Relative to 7vPnC Group After the 2-dose Infant Series
End point description:	
Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations. (n) = number of subjects with a determinate antibody concentration/titer for the specified concomitant antigen.	
End point type	Primary
End point timeframe:	
One month after infant series dose 2 (5 months of age)	

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	118		
Units: EU/mL				
geometric mean (confidence interval 95%)				

Pertussis FHA (n=119,113)	54.74 (48.25 to 62.09)	55.99 (49.55 to 63.28)		
Pertussis PT (n=119,112)	66.26 (59.2 to 74.16)	67.05 (58.75 to 76.52)		
Pertussis PRN (n=119,113)	61.33 (51.78 to 72.65)	61.07 (52.31 to 71.3)		
Pertussis FIM (n=119,113)	21.72 (18.89 to 24.98)	21.77 (18.54 to 25.56)		

Statistical analyses

Statistical analysis title	Analysis of GMC for Pertussis FHA
Statistical analysis description:	
For Pertussis FHA the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
Parameter estimate	Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.16

Notes:

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

Statistical analysis title	Analysis of GMC for Pertussis PT
Statistical analysis description:	
For Pertussis PT the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[20]
Parameter estimate	Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.17

Notes:

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

Statistical analysis title	Analysis of GMC for Pertussis PRN
Statistical analysis description:	
For Pertussis PRN the GMC ratio (13vPnC/7vPnC) was calculated.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series

Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[21]
Parameter estimate	Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.26

Notes:

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

Statistical analysis title	Analysis of GMC for Pertussis FIM

Statistical analysis description:

For Pertussis FIM the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	non-inferiority[22]
Parameter estimate	Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.23

Notes:

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

Primary: Percentage of Subjects in the 13vPnC Group Achieving a Serotype-specific IgG Antibody Concentration >=0.35 mcg/mL Measured 1 Month After the 2-dose Infant Series, Before and After the Toddler Dose

End point title	Percentage of Subjects in the 13vPnC Group Achieving a Serotype-specific IgG Antibody Concentration >=0.35 mcg/mL Measured 1 Month After the 2-dose Infant Series, Before and After the Toddler Dose[23]

End point description:

Percentages of subjects achieving WHO predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n) = number of subjects with a determinate IgG antibody concentration to the given serotype.

End point type	Primary

End point timeframe:

One month after infant series dose 2 (5 months of age), before and after toddler dose (12 months of age)

Notes:

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

End point values	13vPnC After Infant Series Dose 2	13vPnC Before Toddler Dose	13vPnC After Toddler Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	120	120	110	
Units: Percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=107,89,102)	95.3 (89.4 to 98.5)	24.7 (16.2 to 35)	99 (94.7 to 100)	
Common Serotypes - Serotype 6B (n=107,86,102)	40.2 (30.8 to 50.1)	74.4 (63.9 to 83.2)	98 (93.1 to 99.8)	
Common Serotypes - Serotype 9V (n=104,91,101)	85.6 (77.3 to 91.7)	44 (33.6 to 54.8)	98 (93 to 99.8)	
Common Serotypes - Serotype 14 (n=107,88,101)	92.5 (85.8 to 96.7)	92 (84.3 to 96.7)	100 (96.4 to 100)	
Common Serotypes - Serotype 18C (n=111,91,105)	92.8 (86.3 to 96.8)	13.2 (7 to 21.9)	97.1 (91.9 to 99.4)	
Common Serotypes - Serotype 19F (n=109,91,104)	93.6 (87.2 to 97.4)	67 (56.4 to 76.5)	98.1 (93.2 to 99.8)	
Common Serotypes - Serotype 23F (n=111,89,104)	66.7 (57.1 to 75.3)	37.1 (27.1 to 48)	98.1 (93.2 to 99.8)	
Additional Serotypes - Serotype 1 (n=107,88,101)	97.2 (92 to 99.4)	50 (39.1 to 60.9)	100 (96.4 to 100)	
Additional Serotypes - Serotype 3 (n=107,87,102)	86 (77.9 to 91.9)	12.6 (6.5 to 21.5)	88.2 (80.4 to 93.8)	
Additional Serotypes - Serotype 5 (n=103,88,101)	89.3 (81.7 to 94.5)	78.4 (68.4 to 86.5)	100 (96.4 to 100)	
Additional Serotypes - Serotype 6A (n=106,86,99)	79.2 (70.3 to 86.5)	79.1 (69 to 87.1)	98 (92.9 to 99.8)	
Additional Serotypes - Serotype 7F (n=107,91,100)	94.4 (88.2 to 97.9)	71.4 (61 to 80.4)	100 (96.4 to 100)	
Additional Serotypes - Serotype 19A (n=110,91,103)	92.7 (86.2 to 96.8)	86.8 (78.1 to 93)	100 (96.5 to 100)	

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Antibody Concentration in 13vPnC Group After the 2-dose Infant Series, Before and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration in 13vPnC Group After the 2-dose Infant Series, Before and After the Toddler Dose[24]

End point description:

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

End point type	Primary

End point timeframe:

One month after infant series dose 2 (5 months of age) and before and after toddler dose (12 months of age)

Notes:

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

End point values	13vPnC After Infant Series Dose 2	13vPnC Before Toddler Dose	13vPnC After Toddler Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	120	120	110	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4 (n=107,87,87)	1.37 (1.16 to 1.62)	0.21 (0.17 to 0.24)	3.52 (2.91 to 4.26)	
Common Serotypes - Serotype 6B (n=107,85,85)	0.26 (0.21 to 0.33)	0.77 (0.6 to 0.99)	7.67 (5.88 to 10.01)	
Common Serotypes - Serotype 9V (n=104,88,88)	0.87 (0.72 to 1.05)	0.29 (0.24 to 0.36)	2.46 (2.03 to 2.99)	
Common Serotypes - Serotype 14 (n=107,87,87)	1.83 (1.47 to 2.27)	1.34 (1.09 to 1.66)	11.32 (9.27 to 13.83)	
Common Serotypes - Serotype 18C (n=111,91,91)	1.37 (1.14 to 1.64)	0.2 (0.17 to 0.23)	2.14 (1.82 to 2.53)	
Common Serotypes - Serotype 19F (n=109,90,90)	2.38 (1.88 to 3.01)	0.6 (0.46 to 0.79)	7.25 (5.65 to 9.31)	
Common Serotypes - Serotype 23F (n=111,88,88)	0.53 (0.42 to 0.67)	0.24 (0.19 to 0.32)	3.13 (2.59 to 3.78)	
Additional Serotypes - Serotype 1 (n=107,85,85)	1.69 (1.41 to 2.04)	0.39 (0.33 to 0.46)	5.6 (4.6 to 6.82)	
Additional Serotypes - Serotype 3 (n=107,85,85)	0.63 (0.56 to 0.71)	0.14 (0.1 to 0.18)	0.98 (0.78 to 1.22)	
Additional Serotypes - Serotype 5 (n=103,86,86)	0.95 (0.79 to 1.14)	0.59 (0.49 to 0.72)	3.68 (3.04 to 4.45)	
Additional Serotypes - Serotype 6A (n=106,83,83)	0.86 (0.68 to 1.07)	0.81 (0.64 to 1.03)	6.31 (5.06 to 7.87)	
Additional Serotypes - Serotype 7F (n=107,87,87)	2.14 (1.75 to 2.62)	0.56 (0.48 to 0.66)	4.06 (3.42 to 4.83)	
Additional Serotypes - Serotype 19A (n=110,89,89)	1.9 (1.54 to 2.34)	1.01 (0.77 to 1.32)	11.33 (9.29 to 13.83)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving an SBA Titer >=1:8 for Meningococcal C in 13vPnC Group Relative to 7vPnC Group Before and After the Toddler Dose

End point title	Percentage of Subjects Achieving an SBA Titer >=1:8 for Meningococcal C in 13vPnC Group Relative to 7vPnC Group Before and After the Toddler Dose

End point description:

Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations; (n)= number of subjects with a determinate posttoddler dose antibody concentration to the given concomitant antigen.

End point type	Secondary

End point timeframe:

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

End point values	13vPnC Before Toddler Dose	7vPnC Before Toddler Dose	13vPnC After Toddler Dose	7vPnC After Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	102	93	109	98
Units: Percentage of Subjects				
number (confidence interval 95%)	44.1 (34.3 to 54.3)	49.5 (38.9 to 60)	91.7 (84.9 to 96.2)	91.8 (84.5 to 96.4)

Statistical analyses

Statistical analysis title	Meningococcal C: After Toddler Dose

Statistical analysis description:

For Meningococcal C the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 titer was calculated.

Comparison groups	7vPnC After Toddler Dose v 13vPnC After Toddler Dose
Number of subjects included in analysis	207
Analysis specification	Pre-specified
Analysis type	non-inferiority[25]
Parameter estimate	Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	8.1

Notes:

[25] - Non-inferiority was used to assess, but the study has not been powered to show non-inferiority.

Statistical analysis title	Meningococcal C: Before Toddler Dose

Statistical analysis description:

For Meningococcal C the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 titer was calculated.

Comparison groups	13vPnC Before Toddler Dose v 7vPnC Before Toddler Dose
Number of subjects included in analysis	195
Analysis specification	Pre-specified
Analysis type	non-inferiority[26]
Parameter estimate	Difference
Point estimate	-5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.7
upper limit	8.8

Notes:

[26] - Non-inferiority was used to assess, but the study has not been powered to show non-inferiority.

Secondary: Percentage of Subjects Achieving a Predefined Antibody Level for Haemophilus Influenzae Type b in the 13vPnC Group Relative to the 7vPnC Group After the Toddler Dose

End point title	Percentage of Subjects Achieving a Predefined Antibody Level for Haemophilus Influenzae Type b in the 13vPnC Group Relative to the 7vPnC Group After the Toddler Dose

End point description:

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

End point type	Secondary

End point timeframe:

One month after 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	105[27]	96[28]		
Units: Percentage of subjects				
number (confidence interval 95%)				
Hib (PRP) >=0.15 mcg/mL	100 (96.5 to 100)	100 (96.2 to 100)		
Hib (PRP)>=1.0 mcg/mL	99 (94.8 to 100)	100 (96.2 to 100)		

Notes:

[27] - Subjects with determinate posttoddler dose antibody concentration to given concomitant antigen

[28] - Subjects with determinate posttoddler dose antibody concentration to given concomitant antigen

Statistical analyses

Statistical analysis title	Analysis for Hib at 1.0 mcg/mL

Statistical analysis description:

For Hib the difference in percentage between the two groups (13vPnC - 7vPnC) at 1.0 mcg/mL threshold was calculated.

Comparison groups	13vPnC Toddler Dose v 7vPnC Toddler Dose
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	non-inferiority[29]
Parameter estimate	Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	2.8

Notes:

[29] - Non-inferiority was used to assess, but the study has not been powered to show non-inferiority.

Statistical analysis title	Analysis for Hib at 0.15 mcg/mL

Statistical analysis description:

For Hib the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.15 mcg/mL threshold was calculated.

Comparison groups	7vPnC Toddler Dose v 13vPnC Toddler Dose
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	non-inferiority[30]
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	3.8

Notes:

[30] - Non-inferiority was used to assess, but the study has not been powered to show non-inferiority.

Secondary: Geometric Mean Antibody Concentration for Haemophilus Influenzae Type b PRP in 13vPnC Group Relative to 7vPnC Group After the Toddler Dose

End point title	Geometric Mean Antibody Concentration for Haemophilus Influenzae Type b PRP in 13vPnC Group Relative to 7vPnC Group After the Toddler Dose

End point description:

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

End point type	Secondary

End point timeframe:

One month after 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	105[31]	96[32]		
Units: mcg/mL				
geometric mean (confidence interval 95%)	22.22 (17.66 to 27.96)	19.75 (16.05 to 24.3)		

Notes:

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

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

Statistical analyses

Statistical analysis title	Analysis of GMC for Hib PRP

Statistical analysis description:

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

Comparison groups	13vPnC Toddler Dose v 7vPnC Toddler Dose

Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	non-inferiority[33]
Parameter estimate	Ratio
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.53

Notes:

[33] - Non-inferiority was used to assess, but the study has not been powered to show non-inferiority.

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

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

End point description:

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

End point type	Secondary

End point timeframe:

One month after 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	109[34]	98[35]		
Units: titer				
geometric mean (confidence interval 95%)	656.11 (445.46 to 966.38)	771.67 (509.98 to 1167.64)		

Notes:

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

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

Statistical analyses

Statistical analysis title	Analysis of GMC for Meningococcal C

Statistical analysis description:

For Meningococcal C the GMC ratio (13vPnC/7vPnC) was calculated.

Comparison groups	13vPnC Toddler Dose v 7vPnC Toddler Dose

Number of subjects included in analysis	207
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.49

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Local Reactions

End point title	Percentage of Subjects Reporting Pre-Specified Local Reactions

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. The safety population included all subjects who received at least 1 dose of vaccine; (n)= number of subjects reporting yes for at least 1 day or no for all days.

End point type	Other pre-specified

End point timeframe:

During the 4-day period after each dose

End point values	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	139	139	136	122
Units: Percentage of Subjects				
number (not applicable)				
Tenderness-Any (n=123,127,114,96,87,71)	44.7	43.3	42.1	50.7
Tenderness-Significant (n=116,122,97,89,77,58)	1.7	6.6	4.1	3.4
Swelling-Any (n=121,126,106,93,83,68)	24.8	29.4	30.2	39.7
Swelling-Mild (n=120,125,105,93,82,66)	21.7	27.2	28.6	34.8
Swelling-Moderate (n=118,121,98,88,77,60)	6.8	6.6	8.2	11.7
Swelling-Severe (n=115,119,96,88,76,57)	0	0	1	0
Redness-Any (n=122,126,107,99,85,73)	22.1	39.7	39.3	53.4
Redness-Mild (n=122,126,106,99,83,71)	21.3	39.7	37.7	49.3
Redness-Moderate (n=116,119,98,88,78,61)	1.7	0	4.1	16.4
Redness-Severe (n=115,119,97,88,76,57)	0	0	2.1	0

End point values	13vPnC Toddler Dose	7vPnC Dose 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	131	135		
Units: Percentage of Subjects				
number (not applicable)				
Tenderness-Any (n=123,127,114,96,87,71)	44.8	40.6		
Tenderness-Significant (n=116,122,97,89,77,58)	3.9	4.5		
Swelling-Any (n=121,126,106,93,83,68)	30.1	34.4		
Swelling-Mild (n=120,125,105,93,82,66)	28	29		
Swelling-Moderate (n=118,121,98,88,77,60)	3.9	6.8		
Swelling-Severe (n=115,119,96,88,76,57)	0	0		
Redness-Any (n=122,126,107,99,85,73)	38.8	40.4		
Redness-Mild (n=122,126,106,99,83,71)	33.7	37.4		
Redness-Moderate (n=116,119,98,88,78,61)	12.8	3.4		
Redness-Severe (n=115,119,97,88,76,57)	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-Specified Systemic Events

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events

End point description:

Systemic events (fever >= 38 degrees Celsius [C] but <= 39 C, fever >39 C but <= 40 C, fever > 40 C, decreased appetite, irritability, increased sleep, decreased sleep, use of medication (Meds) to prevent symptoms, and use of medication to treat symptoms) were collected using an electronic diary; percentage of subjects with each event was evaluated. Safety population included all subjects who received at least 1 dose of vaccine. (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Other pre-specified

End point timeframe:

During the 4-day period after each dose

End point values	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	139	139	136	122
Units: Percentage of Subjects				
number (not applicable)				
Fever >=38°C but <=39°C (n=116,119,96,88,78,61)	6	3.4	3.1	16.4
Fever >39°C but <=40°C (n=115,119,95,88,76,58)	0.9	0	0	5.2
Fever >40°C (n=115,119,96,88,76,57)	0	0	2.1	0
Decreased appetite (n=120,129,104,98,92,68)	39.2	34.1	35.6	44.1
Irritability (n=128,135,117,119,97,80)	76.6	74.1	71.8	76.3
Increased sleep (n=129,129,114,109,88,71)	69.8	66.7	51.8	40.8
Decreased sleep (n=119,124,98,100,81,67)	32.8	33.9	35.7	44.8
Meds to treat symptoms (n=123,128,108,110,85,72)	43.9	40.6	50.9	58.3
Meds to prevent symptoms (n=122,124,117,103,92,77)	49.2	40.3	48.7	67.5

End point values	13vPnC Toddler Dose	7vPnC Dose 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	131	135		
Units: Percentage of Subjects				
number (not applicable)				
Fever >=38°C but <=39°C (n=116,119,96,88,78,61)	7.7	4.5		
Fever >39°C but <=40°C (n=115,119,95,88,76,58)	0	0		
Fever >40°C (n=115,119,96,88,76,57)	0	0		
Decreased appetite (n=120,129,104,98,92,68)	39.1	37.8		
Irritability (n=128,135,117,119,97,80)	74.2	80.7		
Increased sleep (n=129,129,114,109,88,71)	38.6	56.9		
Decreased sleep (n=119,124,98,100,81,67)	32.1	38		
Meds to treat symptoms (n=123,128,108,110,85,72)	49.4	54.5		
Meds to prevent symptoms (n=122,124,117,103,92,77)	52.2	50.5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events (AEs)/Serious AEs: recorded from sigining of informed consent to 6 months after the last study vaccination. Subjects recorded pre-specified AEs in electronic diary:local reactions; systemic events (up to 4 days after each vaccination)

Adverse event reporting additional description:

MedDRA Version was not captured, here 0.0 is mentioned for dictionary version. Local Reactions (LRs) and Systemic Events (SEs) were to be assessed only for infant series and toddler dose groups.

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 one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and a DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (AE/SAE assessment at 5 months of age, 1 month after the infant series). Pediacel was administered without study vaccine at 3-month visit.

Reporting group title	7vPnC Infant Series

Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and a DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (AE/SAE assessment at 5 months of age, 1 month after the infant series). Pediacel was administered without study vaccine at 3-month visit.

Reporting group title	13vPnC After Infant Series

Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with NeisVac-C and a DT5aP, IPV and Hib conjugate vaccine Pediacel at the 2- and 4-month visits (AE/SAE assessment at 5 months of age, 1 month after the infant dose to before toddler dose). Pediacel was administered without study vaccine at 3-month visit.

Reporting group title	7vPnC After Infant Series

Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with NeisVac-C and a DT5aP, IPV and Hib conjugate vaccine (Pediacel) at the 2- and 4-month visits (AE/SAE assessment at 5 months of age, 1 month after the infant dose to before toddler dose). Pediacel was administered without study vaccine at 3-month visit.

Reporting group title	13vPnC Toddler Series

Reporting group description:

Subjects recieved one single 0.5 mL dose of 13vPnC coadministered with Hib and Menitorix at the 12-month visit (toddler dose). AE/SAE assessment at 1 month after the toddler dose.

Reporting group title	7vPnC Toddler Series

Reporting group description:

Subjects recieved one single 0.5 mL dose of 7vPnC coadministered with Hib and Menitorix at the 12-month visit (toddler dose). AE/SAE assessment at 1 month after the toddler dose.

Reporting group title	13vPnC 6-Month Follow-up

Reporting group description:

Subjects recieved one single 0.5 mL dose of 13vPnC coadministered with Hib and Menitorix at the 12-month visit (AE/SAE assessment at 18 months of age, 6 months after the toddler dose).

Reporting group title	7vPnC 6-Month Follow-up

Reporting group description:

Subjects recieved one single 0.5 mL dose of 7vPnC coadministered with Hib and Menitorix at the 12-month visit (AE/SAE assessment at 18 months of age, 6 months after the toddler dose).

Serious adverse events	13vPnC Infant Series	7vPnC Infant Series	13vPnC After Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 138 (0.72%)	3 / 139 (2.16%)	5 / 138 (3.62%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue injury			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (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
Hemiplegia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (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			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (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

Vomiting			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (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			
Wheezing			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (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
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (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 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (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	7vPnC After Infant Series	13vPnC Toddler Series	7vPnC Toddler Series
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 139 (1.44%)	1 / 130 (0.77%)	2 / 122 (1.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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
Tongue injury			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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
Fall			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
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 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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
Hemiplegia			

subjects affected / exposed	1 / 139 (0.72%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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
Vomiting			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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			
Wheezing			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (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
Cellulitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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
Lower respiratory tract infection			

subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (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	1 / 139 (0.72%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
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	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 138 (1.45%)	0 / 139 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue injury			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (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	1 / 138 (0.72%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (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	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (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	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (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 Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	128 / 138 (92.75%)	124 / 139 (89.21%)	9 / 138 (6.52%)
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	2	0
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	9 / 138 (6.52%)	7 / 139 (5.04%)	0 / 138 (0.00%)
occurrences (all)	12	7	0
Injection site erythema			
subjects affected / exposed	1 / 138 (0.72%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	1	2	0
Feeling hot			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Fever >=38 degree C but <=39 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	7 / 116 (6.03%)	4 / 119 (3.36%)	0 / 138 (0.00%)
occurrences (all)	7	4	0
Fever >39 degrees C but <=40 degrees C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[2]	1 / 115 (0.87%)	0 / 119 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	47 / 120 (39.17%)	44 / 129 (34.11%)	0 / 138 (0.00%)
occurrences (all)	47	44	0
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	98 / 128 (76.56%)	100 / 135 (74.07%)	0 / 138 (0.00%)
occurrences (all)	98	100	0
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	90 / 129 (69.77%)	86 / 129 (66.67%)	0 / 138 (0.00%)
occurrences (all)	90	86	0
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	39 / 119 (32.77%)	42 / 124 (33.87%)	0 / 138 (0.00%)
occurrences (all)	39	42	0
Fever >=38 degrees C but <=39 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	3 / 96 (3.13%)	4 / 88 (4.55%)	0 / 138 (0.00%)
occurrences (all)	3	4	0
Fever >40 degrees C Infant Series	Additional description: Subjects affected and occurrences for SEs is same as		

Dose 2	data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	2 / 96 (2.08%)	0 / 88 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Decreased appetite Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	37 / 104 (35.58%)	37 / 98 (37.76%)	0 / 138 (0.00%)
occurrences (all)	37	37	0
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	84 / 117 (71.79%)	96 / 119 (80.67%)	0 / 138 (0.00%)
occurrences (all)	84	96	0
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	59 / 114 (51.75%)	62 / 109 (56.88%)	0 / 138 (0.00%)
occurrences (all)	59	62	0
Decreased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	35 / 98 (35.71%)	38 / 100 (38.00%)	0 / 138 (0.00%)
occurrences (all)	35	38	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	0	1
Drug hypersensitivity			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	29 / 138 (21.01%)	16 / 139 (11.51%)	1 / 138 (0.72%)
occurrences (all)	32	17	1
Rhinorrhoea			
subjects affected / exposed	1 / 138 (0.72%)	7 / 139 (5.04%)	0 / 138 (0.00%)
occurrences (all)	1	7	0
Wheezing			
subjects affected / exposed	1 / 138 (0.72%)	2 / 139 (1.44%)	1 / 138 (0.72%)
occurrences (all)	1	3	1
Nasal congestion			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Sneezing			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Grunting			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Crying			
subjects affected / exposed	2 / 138 (1.45%)	4 / 139 (2.88%)	0 / 138 (0.00%)
occurrences (all)	4	4	0
Insomnia			
subjects affected / exposed	1 / 138 (0.72%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	1	2	0
Agitation			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Staring			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	0	1
Investigations			
Physical examination abnormal			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	2	1	0
Radius fracture			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	2 / 138 (1.45%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Traumatic haematoma			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			

Dacryostenosis congenital			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Lymphangioma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	0	1
Cardiac disorders			
Cyanosis			
subjects affected / exposed	2 / 138 (1.45%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
High-pitched crying			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Somnolence			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Hypertonia			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			

subjects affected / exposed	7 / 138 (5.07%)	13 / 139 (9.35%)	0 / 138 (0.00%)
occurrences (all)	7	13	0
Eye discharge			
subjects affected / exposed	5 / 138 (3.62%)	3 / 139 (2.16%)	0 / 138 (0.00%)
occurrences (all)	6	3	0
Ocular hyperaemia			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Astigmatism			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Hypermetropia			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	24 / 138 (17.39%)	17 / 139 (12.23%)	0 / 138 (0.00%)
occurrences (all)	32	17	0
Vomiting			
subjects affected / exposed	19 / 138 (13.77%)	11 / 139 (7.91%)	0 / 138 (0.00%)
occurrences (all)	25	12	0
Teething			
subjects affected / exposed	11 / 138 (7.97%)	9 / 139 (6.47%)	0 / 138 (0.00%)
occurrences (all)	12	9	0
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 138 (3.62%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	5	2	0
Constipation			
subjects affected / exposed	1 / 138 (0.72%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	1	2	0
Infantile spitting up			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	2	1	0

Stomach discomfort			
subjects affected / exposed	2 / 138 (1.45%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Abdominal discomfort			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Reflux oesophagitis			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	11 / 138 (7.97%)	5 / 139 (3.60%)	1 / 138 (0.72%)
occurrences (all)	13	6	1
Rash			
subjects affected / exposed	3 / 138 (2.17%)	5 / 139 (3.60%)	0 / 138 (0.00%)
occurrences (all)	3	5	0
Dermatitis diaper			
subjects affected / exposed	2 / 138 (1.45%)	5 / 139 (3.60%)	0 / 138 (0.00%)
occurrences (all)	2	7	0
Dry skin			
subjects affected / exposed	2 / 138 (1.45%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	2	3	0
Dermatitis atopic			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	0	1
Dermatitis allergic			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Eczema infantile			
subjects affected / exposed	1 / 138 (0.72%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	1	2	0
Erythema			
subjects affected / exposed	0 / 138 (0.00%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	0	2	0
Urticaria			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Dermatitis contact			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Heat rash			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Skin discolouration			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Umbilical erythema			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[13]	55 / 123 (44.72%)	55 / 127 (43.31%)	0 / 138 (0.00%)
occurrences (all)	55	55	0
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	2 / 116 (1.72%)	8 / 122 (6.56%)	0 / 138 (0.00%)
occurrences (all)	2	8	0
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	30 / 121 (24.79%)	37 / 126 (29.37%)	0 / 138 (0.00%)
occurrences (all)	30	37	0
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	26 / 120 (21.67%)	34 / 125 (27.20%)	0 / 138 (0.00%)
occurrences (all)	26	34	0
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	8 / 118 (6.78%)	8 / 121 (6.61%)	0 / 138 (0.00%)
occurrences (all)	8	8	0
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	27 / 122 (22.13%)	50 / 126 (39.68%)	0 / 138 (0.00%)
occurrences (all)	27	50	0
Erythema (Mild) Infant Series Dose 1	Additional description: Subjects affected and occurrences for LRs is same as		

and Toddler Dose	data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	26 / 122 (21.31%)	50 / 126 (39.68%)	0 / 138 (0.00%)
occurrences (all)	26	50	0
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	2 / 116 (1.72%)	0 / 119 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Tenderness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	48 / 114 (42.11%)	39 / 96 (40.63%)	0 / 138 (0.00%)
occurrences (all)	48	39	0
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: l 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	4 / 97 (4.12%)	4 / 89 (4.49%)	0 / 138 (0.00%)
occurrences (all)	4	4	0
Induration (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	32 / 106 (30.19%)	32 / 93 (34.41%)	0 / 138 (0.00%)
occurrences (all)	32	32	0
Induration (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[24]	30 / 105 (28.57%)	27 / 93 (29.03%)	0 / 138 (0.00%)
occurrences (all)	30	27	0
Induration (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	8 / 98 (8.16%)	6 / 88 (6.82%)	0 / 138 (0.00%)
occurrences (all)	8	6	0
Induration (Severe) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	1 / 96 (1.04%)	0 / 88 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Erythema (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	42 / 107 (39.25%)	40 / 99 (40.40%)	0 / 138 (0.00%)
occurrences (all)	42	40	0
Erythema (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	40 / 106 (37.74%)	37 / 99 (37.37%)	0 / 138 (0.00%)
occurrences (all)	40	37	0
Erythema (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	4 / 98 (4.08%)	3 / 88 (3.41%)	0 / 138 (0.00%)
occurrences (all)	4	3	0
Erythema (Severe) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[30]	2 / 97 (2.06%)	0 / 88 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Rhinitis subjects affected / exposed	32 / 138 (23.19%)	26 / 139 (18.71%)	1 / 138 (0.72%)
occurrences (all)	40	39	1
Upper respiratory tract infection subjects affected / exposed	16 / 138 (11.59%)	19 / 139 (13.67%)	0 / 138 (0.00%)
occurrences (all)	19	21	0
Otitis media subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	1 / 138 (0.72%)
occurrences (all)	1	1	1
Bronchiolitis subjects affected / exposed	0 / 138 (0.00%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis subjects affected / exposed	15 / 138 (10.87%)	14 / 139 (10.07%)	0 / 138 (0.00%)
occurrences (all)	18	19	0
Rubella subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	0	1
Lower respiratory tract infection subjects affected / exposed	7 / 138 (5.07%)	4 / 139 (2.88%)	0 / 138 (0.00%)
occurrences (all)	8	5	0
Varicella subjects affected / exposed	2 / 138 (1.45%)	8 / 139 (5.76%)	0 / 138 (0.00%)
occurrences (all)	2	8	0
Gastroenteritis subjects affected / exposed	5 / 138 (3.62%)	4 / 139 (2.88%)	0 / 138 (0.00%)
occurrences (all)	6	4	0
Oral candidiasis subjects affected / exposed	5 / 138 (3.62%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	5	2	0
Viral infection			

subjects affected / exposed	4 / 138 (2.90%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	4	2	0
Herpes zoster			
subjects affected / exposed	2 / 138 (1.45%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	2	2	0
Injection site infection			
subjects affected / exposed	1 / 138 (0.72%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	1	2	0
Viral skin infection			
subjects affected / exposed	2 / 138 (1.45%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	2	1	0
Ear infection			
subjects affected / exposed	0 / 138 (0.00%)	2 / 139 (1.44%)	0 / 138 (0.00%)
occurrences (all)	0	2	0
Eczema infected			
subjects affected / exposed	2 / 138 (1.45%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	2	0	0
Candidiasis			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Dermatitis infected			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	1	1	0
Anorexia			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	0 / 138 (0.00%)
occurrences (all)	0	1	0
Weight gain poor			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	1	0	0
Lactose intolerance			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	7vPnC After Infant Series	13vPnC Toddler Series	7vPnC Toddler Series
Total subjects affected by non-serious adverse events			

subjects affected / exposed	8 / 139 (5.76%)	87 / 130 (66.92%)	82 / 122 (67.21%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 139 (0.00%)	5 / 130 (3.85%)	6 / 122 (4.92%)
occurrences (all)	0	5	6
Injection site erythema			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0

Fever >=38 degree C but <=39 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 139 (0.00%)	6 / 78 (7.69%)	10 / 61 (16.39%)
occurrences (all)	0	6	10
Fever >39 degrees C but <=40 degrees C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 139 (0.00%)	0 / 76 (0.00%)	3 / 58 (5.17%)
occurrences (all)	0	0	3
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 139 (0.00%)	36 / 92 (39.13%)	30 / 68 (44.12%)
occurrences (all)	0	36	30
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 139 (0.00%)	72 / 97 (74.23%)	61 / 80 (76.25%)
occurrences (all)	0	72	61
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 139 (0.00%)	34 / 88 (38.64%)	29 / 71 (40.85%)
occurrences (all)	0	34	29
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[6]	0 / 139 (0.00%)	26 / 81 (32.10%)	30 / 67 (44.78%)
occurrences (all)	0	26	30
Fever >=38 degrees C but <=39 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Fever >40 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 139 (0.00%) 0	0 / 130 (0.00%) 0	0 / 122 (0.00%) 0
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	0 / 130 (0.00%) 0	0 / 122 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	1 / 130 (0.77%) 1	0 / 122 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	3 / 139 (2.16%) 3	0 / 130 (0.00%) 0	0 / 122 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	10 / 130 (7.69%) 10	10 / 122 (8.20%) 11
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	1 / 130 (0.77%) 1	1 / 122 (0.82%) 1
Wheezing subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	1 / 130 (0.77%) 1	0 / 122 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	0 / 130 (0.00%) 0	0 / 122 (0.00%) 0
Sneezing subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	0 / 130 (0.00%) 0	0 / 122 (0.00%) 0
Pharyngolaryngeal pain subjects affected / exposed occurrences (all)	0 / 139 (0.00%) 0	0 / 130 (0.00%) 0	1 / 122 (0.82%) 1
Dysphonia			

subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Grunting			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Staring			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Investigations			
Physical examination abnormal			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Radius fracture			

subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Head injury			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Dacryostenosis congenital			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Lymphangioma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
High-pitched crying			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Hypertonia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 139 (0.00%)	3 / 130 (2.31%)	4 / 122 (3.28%)
occurrences (all)	0	3	5
Eye discharge			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Astigmatism			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Hypermetropia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 139 (0.00%)	12 / 130 (9.23%)	13 / 122 (10.66%)
occurrences (all)	0	14	14
Vomiting			
subjects affected / exposed	0 / 139 (0.00%)	12 / 130 (9.23%)	13 / 122 (10.66%)
occurrences (all)	0	13	14
Teething			
subjects affected / exposed	0 / 139 (0.00%)	4 / 130 (3.08%)	3 / 122 (2.46%)
occurrences (all)	0	4	3
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Infantile spitting up			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Stomach discomfort			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Reflux oesophagitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	2 / 139 (1.44%)	1 / 130 (0.77%)	1 / 122 (0.82%)
occurrences (all)	2	1	1
Rash			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Dermatitis diaper			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0

Dry skin			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Eczema infantile			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0

Umbilical erythema			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 139 (0.00%)	39 / 87 (44.83%)	36 / 71 (50.70%)
occurrences (all)	0	39	36
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 139 (0.00%)	3 / 77 (3.90%)	2 / 58 (3.45%)
occurrences (all)	0	3	2
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 139 (0.00%)	25 / 83 (30.12%)	27 / 68 (39.71%)
occurrences (all)	0	25	27
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 139 (0.00%)	23 / 82 (28.05%)	23 / 66 (34.85%)
occurrences (all)	0	23	23
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 139 (0.00%)	3 / 77 (3.90%)	7 / 60 (11.67%)
occurrences (all)	0	3	7
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence		

	from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 139 (0.00%)	33 / 85 (38.82%)	39 / 73 (53.42%)
occurrences (all)	0	33	39
Erythema (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 139 (0.00%)	28 / 83 (33.73%)	35 / 71 (49.30%)
occurrences (all)	0	28	35
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 139 (0.00%)	10 / 78 (12.82%)	10 / 61 (16.39%)
occurrences (all)	0	10	10
Tenderness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: l 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[23]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Induration (Severe) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Erythema (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[29]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Erythema (Severe) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[30]	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Rhinitis subjects affected / exposed	0 / 139 (0.00%)	11 / 130 (8.46%)	10 / 122 (8.20%)
occurrences (all)	0	11	10
Upper respiratory tract infection subjects affected / exposed	1 / 139 (0.72%)	4 / 130 (3.08%)	4 / 122 (3.28%)
occurrences (all)	1	4	4
Otitis media subjects affected / exposed	1 / 139 (0.72%)	1 / 130 (0.77%)	2 / 122 (1.64%)
occurrences (all)	1	1	2
Bronchiolitis subjects affected / exposed	1 / 139 (0.72%)	1 / 130 (0.77%)	1 / 122 (0.82%)
occurrences (all)	1	1	1
Nasopharyngitis subjects affected / exposed	1 / 139 (0.72%)	9 / 130 (6.92%)	8 / 122 (6.56%)
occurrences (all)	1	9	9
Rubella subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection subjects affected / exposed	0 / 139 (0.00%)	8 / 130 (6.15%)	2 / 122 (1.64%)
occurrences (all)	0	8	2
Varicella subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0

Gastroenteritis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 139 (0.00%)	2 / 130 (1.54%)	2 / 122 (1.64%)
occurrences (all)	0	2	2
Herpes zoster			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Injection site infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Viral skin infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 139 (0.00%)	5 / 130 (3.85%)	3 / 122 (2.46%)
occurrences (all)	0	5	4
Eczema infected			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 139 (0.00%)	2 / 130 (1.54%)	0 / 122 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0

Skin candida			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	1 / 122 (0.82%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Eye infection			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	2 / 122 (1.64%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Anorexia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			

subjects affected / exposed	0 / 139 (0.00%)	0 / 130 (0.00%)	0 / 122 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 139 (0.00%)	1 / 130 (0.77%)	0 / 122 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 138 (0.72%)	1 / 139 (0.72%)	
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Gait disturbance			
subjects affected / exposed	1 / 138 (0.72%)	0 / 139 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Injection site erythema			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Feeling hot			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Injection site bruising			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Vessel puncture site haematoma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Injection site induration			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Fever >=38 degree C but <=39 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 138 (0.00%)	0 / 139 (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 SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[6] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Fever >=38 degrees C but <=39 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Fever >40 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Decreased appetite Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[10]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Decreased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Drug hypersensitivity			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 138 (0.00%)	1 / 139 (0.72%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Sneezing			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Grunting			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Agitation			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Restlessness			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Staring			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Investigations			
Physical examination abnormal			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Cardiac murmur			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Radius fracture			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Head injury			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Traumatic haematoma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Dacryostenosis congenital			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Lymphangioma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
High-pitched crying			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	

Hypertonia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Lethargy			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Eye discharge			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Astigmatism			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dacryostenosis acquired			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Hypermetropia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Teething			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Infantile spitting up			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Stomach discomfort			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Abdominal discomfort			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Frequent bowel movements			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Reflux oesophagitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	

Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dermatitis diaper			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Eczema infantile			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dermatitis contact			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Heat rash			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Rash erythematous			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Rash papular			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Skin discolouration			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Umbilical erythema			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local			

Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[21]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: l 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Induration (Severe) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Erythema (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Erythema (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[28] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Erythema (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[29] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Erythema (Severe) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[30] occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Infections and infestations			
Rhinitis subjects affected / exposed occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Otitis media subjects affected / exposed occurrences (all)	0 / 138 (0.00%) 0	0 / 139 (0.00%) 0	
Bronchiolitis			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Rubella			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Varicella			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Injection site infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Viral skin infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Eczema infected			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Candidiasis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Dermatitis infected			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Impetigo			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Skin candida			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Eye infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			

subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Anorexia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Increased appetite			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Weight gain poor			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	0	
Lactose intolerance			
subjects affected / exposed	0 / 138 (0.00%)	0 / 139 (0.00%)	
occurrences (all)	0	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.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 July 2007	An amendment was made to change the medical monitor and to decrease the sample size from 600 to a minimum of 250 subjects in order to reach a target enrollment number within a reasonable time frame. Because the sample size was decreased, the statistical approach was changed from non-inferiority testing with regard to concomitant vaccine immunogenicity to descriptive statistics with a given level of precision. Given the level of precision for the immunogenicity assessments, the amended protocol will provide important information on the use of 13vPnC in the United Kingdom schedule to support licensure and provide information to vaccine recommending bodies.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported