



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 Spain.

Summary

EudraCT number	2005-004772-21
Trial protocol	ES
Global end of trial date	28 July 2008

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	01 August 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-501
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00368966
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851097

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)	EMA-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	23 September 2008
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 July 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immune response induced by Meningitec given with 13-valent pneumococcal conjugate vaccine (13vPnC) is noninferior to the immune response induced by Meningitec given with 7-valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the 2-dose Meningitec infant series.

To demonstrate that the immune responses induced by Infanrix hexa given with 13vPnC are noninferior to the immune responses induced by Infanrix hexa given with 7vPnC when measured 1 month after the 3-dose infant series.

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	13 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	Spain: 619
Worldwide total number of subjects	619
EEA total number of subjects	619

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	7
Infants and toddlers (28 days-23 months)	612
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 Spain from October 2006 to December 2006.

Pre-assignment

Screening details:

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

Period 1

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

Arms

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

Arm description:

Subjects received 13vPnC coadministered with a combination vaccine diphtheria, tetanus, and pertussis (acellular) vaccine (DTPa), hepatitis B virus vaccine (HBV), inactivated poliovirus (IPV), and Haemophilus influenzae type b (Hib) vaccine (Infanrix hexa) and a meningococcal C conjugate vaccine (Meningitec) at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months. At Dose 2, one subject was randomized in 13vPnC but incorrectly given 7vPnC.

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 milliliter (mL) dose of 13vPnC at 2, 4 and 6 months.

Investigational medicinal product name	Meningitec
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 Meningitec at 2 and 4 months.

Investigational medicinal product name	Infanrix hexa
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 combination vaccine DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) at 2, 4 and 6 months.

Arm title	7vPnC Infant Series
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Arm description:

Subjects received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with

Infanrix hexa at 6 months. At dose 1, one subject was randomized to 7vPnC but given 13vPnC vaccine; 1 was withdrawn before receiving 7vPnC vaccine. At Dose 3, one subject was randomized in 7vPnC but incorrectly given 13vPnC.

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, 4 and 6 months.

Investigational medicinal product name	Meningitec
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 Meningitec at 2 and 4 months.

Investigational medicinal product name	Infanrix hexa
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 Infanrix hexa at 2, 4 and 6 months.

Number of subjects in period 1	13vPnC Infant Series	7vPnC Infant Series
Started	315	304
Vaccinated Dose 1	314	302
Vaccinated Dose 2	307	298
Vaccinated Dose 3	301	296
Completed	299	294
Not completed	16	10
Randomization error	-	1
Consent withdrawn by subject	11	6
Failed to return	1	-
Adverse Event	-	1
'Protocol Violation '	2	1
Lost to follow-up	2	-
'Failed to meet eligibility criteria '	-	1

Period 2

Period 2 title	After Infant
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
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Arm title	13vPnC After Infant Series
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Arm description:

Included subjects who received 13vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months.

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

Arm title	7vPnC After Infant Series
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Arm description:

Included subjects who received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months.

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

Number of subjects in period 2	13vPnC After Infant Series	7vPnC After Infant Series
Started	299	294
Completed	293	289
Not completed	6	5
Consent withdrawn by subject	1	1
Failed to return	3	1
Adverse Event	1	2
Death	1	-
Lost to follow-up	-	1

Period 3

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	13vPnC Toddler Dose
Arm description: Subjects received combination vaccine measles, mumps, rubella live virus (MMR II) at 12 months. Subjects received 13vPnC coadministered with DTPa, IPV, and Hib vaccine (Infanrix-IPV+Hib) and Meningitec at 15 months.	
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 15 months.	
Investigational medicinal product name	Meningitec
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 Meningitec at 15 months	
Investigational medicinal product name	Infanrix-IPV+Hib
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 Infanrix-IPV+Hib at 15 months.	
Investigational medicinal product name	MMR II
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects received one single 0.5 mL dose of MMR II at 12 months.	
Arm title	7vPnC Toddler Dose
Arm description: Subjects received combination vaccine MMR II at 12 months . Subjects received one single 7vPnC coadministered with vaccine Infanrix-IPV+Hib and Meningitec vaccine at 15 months.	
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 15 months.	
Investigational medicinal product name	Meningitec
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 Meningitec at 15 months.

Investigational medicinal product name	Infanrix-IPV+Hib
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 Infanrix-IPV+Hib at 15 months.

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

Dosage and administration details:

Subjects received one single 0.5 mL dose of MMR II at 12 months.

Number of subjects in period 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Started	293	289
Completed	292	286
Not completed	1	3
Consent withdrawn by subject	1	1
Lost to follow-up	-	2

Baseline characteristics

Reporting groups

Reporting group title	13vPnC Infant Series
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Reporting group description:

Subjects received 13vPnC coadministered with a combination vaccine diphtheria, tetanus, and pertussis (acellular) vaccine (DTPa), hepatitis B virus vaccine (HBV), inactivated poliovirus (IPV), and Haemophilus influenzae type b (Hib) vaccine (Infanrix hexa) and a meningococcal C conjugate vaccine (Meningitec) at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months. At Dose 2, one subject was randomized in 13vPnC but incorrectly given 7vPnC.

Reporting group title	7vPnC Infant Series
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Reporting group description:

Subjects received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months. At dose 1, one subject was randomized to 7vPnC but given 13vPnC vaccine; 1 was withdrawn before receiving 7vPnC vaccine. At Dose 3, one subject was randomized in 7vPnC but incorrectly given 13vPnC.

Reporting group values	13vPnC Infant Series	7vPnC Infant Series	Total
Number of subjects	315	304	619
Age categorical Units: Subjects			
Age continuous Units: months arithmetic mean standard deviation	2.1 ± 0.5	2.1 ± 0.5	-
Gender categorical Units: Subjects			
Female	148	152	300
Male	167	152	319

End points

End points reporting groups

Reporting group title	13vPnC Infant Series
Reporting group description: Subjects received 13vPnC coadministered with a combination vaccine diphtheria, tetanus, and pertussis (acellular) vaccine (DTPa), hepatitis B virus vaccine (HBV), inactivated poliovirus (IPV), and Haemophilus influenzae type b (Hib) vaccine (Infanrix hexa) and a meningococcal C conjugate vaccine (Meningitec) at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months. At Dose 2, one subject was randomized in 13vPnC but incorrectly given 7vPnC.	
Reporting group title	7vPnC Infant Series
Reporting group description: Subjects received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months. At dose 1, one subject was randomized to 7vPnC but given 13vPnC vaccine; 1 was withdrawn before receiving 7vPnC vaccine. At Dose 3, one subject was randomized in 7vPnC but incorrectly given 13vPnC.	
Reporting group title	13vPnC After Infant Series
Reporting group description: Included subjects who received 13vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months.	
Reporting group title	7vPnC After Infant Series
Reporting group description: Included subjects who received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months.	
Reporting group title	13vPnC Toddler Dose
Reporting group description: Subjects received combination vaccine measles, mumps, rubella live virus (MMR II) at 12 months. Subjects received 13vPnC coadministered with DTPa, IPV, and Hib vaccine (Infanrix-IPV+Hib) and Meningitec at 15 months.	
Reporting group title	7vPnC Toddler Dose
Reporting group description: Subjects received combination vaccine MMR II at 12 months . Subjects received one single 7vPnC coadministered with vaccine Infanrix-IPV+Hib and Meningitec vaccine at 15 months.	
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 a combination vaccine Infanrix hexa and Meningitec at 2 months (infant series).	
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 a combination vaccine Infanrix hexa and Meningitec at 2 months (infant series).	
Subject analysis set title	13vPnC Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 13vPnC coadministered with a combination vaccine Infanrix hexa and Meningitec at 4 months (infant series).	
Subject analysis set title	7vPnC Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 7vPnC coadministered with a combination vaccine Infanrix hexa and Meningitec at 4 months (infant series).	

Subject analysis set title	13vPnC Dose 3
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix hexa at 6 months (infant series).	
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 Infanrix-IPV+Hib and Meningitec at 15 months (toddler dose).	
Subject analysis set title	7vPnC Dose 3
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix hexa at 6 months (infant series).	
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 Infanrix-IPV+Hib and Meningitec at 15 months (toddler dose).	
Subject analysis set title	13vPnC After Infant Series Dose 3
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received 13vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months (infant series).	
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 a combination vaccine Infanrix hexa and Meningitec at 2 and 4 months (infant series).	
Subject analysis set title	13vPnC After Infant Series
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received 13vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months (infant series).	
Subject analysis set title	7vPnC After Infant Series
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months (infant series).	
Subject analysis set title	13vPnC After the Toddler Dose
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix-IPV+Hib and Meningitec at 15 months (toddler dose).	
Subject analysis set title	7vPnC After Infant Series Dose 3
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received 7vPnC coadministered with a combination DTPa, HBV, IPV, and Hib vaccine (Infanrix hexa) and a Meningitec vaccine at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months (infant series).	
Subject analysis set title	7vPnC After the Toddler Dose

Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix-IPV+Hib and Meningitec at 15 months.	
Primary: Percentage of Subjects Achieving Predefined Meningococcal C Serum Bactericidal Assay (SBA) Titer of $\geq 1:8$, and a Predefined Antibody Level for Diphtheria in 13vPnC Group Relative to 7vPnC Group After 2-doses of the Infant Series	
End point title	Percentage of Subjects Achieving Predefined Meningococcal C Serum Bactericidal Assay (SBA) Titer of $\geq 1:8$, and a Predefined Antibody Level for Diphtheria in 13vPnC Group Relative to 7vPnC Group After 2-doses of the Infant Series
End point description:	
Percentage of subjects achieving predefined antibody threshold levels; greater than or equal to ($\geq$) 1:8 for meningococcal C SBA titer and ≥ 0.10 or ≥ 0.01 International Units Per Milliliter (IU/mL) for diphtheria along with the corresponding 95 percentage (%) Confidence Interval (CI) are presented. Evaluable immunogenicity (per protocol) population was the primary analysis 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 2-doses of the infant series (5 months of age)	

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	297	284		
Units: Percentage of Subjects				
number (confidence interval 95%)				
Meningococcal C $\geq 1:8$	98.3 (96.1 to 99.5)	98.9 (96.9 to 99.8)		
Diphtheria ≥ 0.10 IU/mL	95.9 (93 to 97.9)	94.7 (91.4 to 97)		
Diphtheria ≥ 0.01 IU/mL	100 (98.8 to 100)	100 (98.7 to 100)		

Statistical analyses

Statistical analysis title	Meningococcal C $\geq 1:8$
Statistical analysis description:	
For Meningococcal C the difference in percentage between the two groups (13vPnC - 7vPnC) at $\geq 1:8$ threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) greater than ($>$) -10%.	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series

Number of subjects included in analysis	581
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	1.6

Statistical analysis title	Diphtheria $\geq$ 0.10 IU/mL
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Statistical analysis description:

For Diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at $\geq$ 0.10 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	581
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	4.9

Statistical analysis title	Diphtheria $\geq$ 0.01 IU/mL
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Statistical analysis description:

For Diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at $\geq$ 0.01 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	581
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

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

End point title	Geometric Mean Titer (GMT) of Meningococcal C in 13vPnC Group Relative to 7vPnC Group After 2-doses of the Infant Series
End point description: The evaluable immunogenicity (per protocol) population was the primary analysis 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 2-doses of the infant series (5 months of age)	

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	297	284		
Units: titer				
geometric mean (confidence interval 95%)	191.22 (167.72 to 218.02)	266.19 (234.86 to 301.71)		

Statistical analyses

Statistical analysis title	GMT ratio for Meningococcal C
Statistical analysis description: For Meningococcal C the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for immune response induced by Meningitec was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).	
Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	581
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.86

Primary: Geometric Mean Antibody Concentration (GMC) for Diphtheria in 13vPnC Group Relative to 7vPnC Group After 2-doses of the Infant Series

End point title	Geometric Mean Antibody Concentration (GMC) for Diphtheria in 13vPnC Group Relative to 7vPnC Group After 2-doses of the Infant Series
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End point description:

The evaluable immunogenicity (per protocol) population was the primary analysis 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
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End point timeframe:

One month after 2-doses of the infant series (5 months of age)

End point values	13vPnC Infant Series	7vPnC Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296	284		
Units: IU/mL				
geometric mean (confidence interval 95%)	0.51 (0.47 to 0.57)	0.63 (0.57 to 0.7)		

Statistical analyses

Statistical analysis title	GMC ratio for Diphtheria
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Statistical analysis description:

For Diphtheria the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for immune response induced by Meningitec 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).

Comparison groups	13vPnC Infant Series v 7vPnC Infant Series
Number of subjects included in analysis	580
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.94

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions

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

Local reactions were collected using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (Sig) (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling or redness present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (Mod) (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. 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	Primary
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End point timeframe:

During the 4-day period after each dose

Notes:

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

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

End point values	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	314	300	306	298
Units: percentage of subjects				
number (not applicable)				
Tenderness-Any (n=275,270,227,232,217,215,193,170)	49.5	43.3	45.4	46.6
Tenderness- Sig(n=247,250,192,203,181,171,136,1	2.8	2.8	4.2	3.9
Swelling-Any (n=252,254,206,212,203,188,153,140)	19	14.2	28.2	23.1
Swelling-Mild (n=251,254,206,212,201,186,151,132)	16.3	14.2	25.7	20.3
Swelling-Mod (n=247,248,191,201,180,173,136,124)	4.3	1.6	5.8	4.5
Swelling- Severe(n=246,247,191,201,176,171,13	0	0	0	0
Redness-Any (n=255,251,211,217,203,198,159,146)	22	19.1	34.1	30.9
Redness-Mild (n=254,251,210,215,203,195,157,141)	20.1	18.3	32.4	30.2
Redness-Mod (n=247,247,192,203,177,175,137,120)	2.4	1.2	3.1	2.5
Redness-Severe (n=246,247,191,201,176,171,131,113)	0	0	0	0

End point values	13vPnC Dose 3	7vPnC Dose 3	13vPnC Toddler Dose	7vPnC Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	301	295	293	289
Units: percentage of subjects				
number (not applicable)				
Tenderness-Any (n=275,270,227,232,217,215,193,170)	47.9	41.9	64.2	64.7
Tenderness- Sig(n=247,250,192,203,181,171,136,1	6.1	0	5.9	6.8
Swelling-Any (n=252,254,206,212,203,188,153,140)	27.6	28.2	33.3	30.7
Swelling-Mild (n=251,254,206,212,201,186,151,132)	26.4	25.8	31.1	24.2
Swelling-Mod (n=247,248,191,201,180,173,136,124)	5.6	4	11.8	12.9
Swelling- Severe(n=246,247,191,201,176,171,13	0	0	0	0
Redness-Any (n=255,251,211,217,203,198,159,146)	31	34.8	40.9	41.1
Redness-Mild (n=254,251,210,215,203,195,157,141)	29.1	33.3	35	37.6
Redness-Mod (n=247,247,192,203,177,175,137,120)	4.5	5.1	13.1	12.5

Redness-Severe (n=246,247,191,201,176,171,131,113)	0	0	0	0
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Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events ^[2]
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End point description:

Systemic events (fever [Fv] ≥ 37.5 degrees Celsius [C], fever ≥ 38 C but ≤ 39 C, fever >39 C but ≤ 40 C, fever > 40 C, decreased [Decr] appetite, irritability, increased [Incr] sleep, decreased sleep, hives, use of medication [Med] to treat symptoms [sx], and use of medication to prevent symptoms) were reported using an electronic diary. 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	Primary
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End point timeframe:

During the 4-day period after each dose

Notes:

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

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

End point values	13vPnC Dose 1	7vPnC Dose 1	13vPnC Dose 2	7vPnC Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	314	300	306	298
Units: percentage of subjects				
number (not applicable)				
Fv $\geq 38^{\circ}\text{C}$, $\leq 39^{\circ}\text{C}$ (n=262,253,213,223,198,196,162,145)	30.5	24.5	40.4	41.7
Fv $>39^{\circ}\text{C}$, $\leq 40^{\circ}\text{C}$ (n=249,247,194,204,177,174,135,118)	0.8	0.8	2.6	2.5
Fv $>40^{\circ}\text{C}$ (n=249,247,192,201,176,171,132,113)	0	0	0	0
Decr appetite (n=269,258,226,229,219,204,174,147)	39.8	36.8	45.1	44.5
Irritability (n=276,267,234,244,229,221,183,170)	51.4	42.7	64.5	61.5
Incr sleep (n=273,269,218,221,206,203,160,145)	53.5	51.3	46.8	41.6
Decr sleep (n=263,255,218,223,205,190,151,129)	34.6	24.7	36.2	29.6
Med-treat sx (n=267,256,232,243,216,209,176,163)	50.6	46.9	60.3	61.3
Med-prevent sx (n=269,258,231,237,222,211,178,159)	49.1	47.7	58.4	58.6

End point values	13vPnC Dose 3	7vPnC Dose 3	13vPnC	7vPnC Toddler
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			Toddler Dose	Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	301	295	293	289
Units: percentage of subjects				
number (not applicable)				
Fv >= 38°C, <= 39°C (n=262,253,213,223,198,196,162,145)	34.3	38.3	38.9	44.8
Fv > 39°C, <= 40°C (n=249,247,194,204,177,174,135,118)	5.6	5.2	8.1	6.8
Fv > 40°C (n=249,247,192,201,176,171,132,113)	0	0	0.8	0
Decr appetite (n=269,258,226,229,219,204,174,147)	47	42.6	53.4	47.6
Irritability (n=276,267,234,244,229,221,183,170)	57.2	58.8	61.7	61.8
Incr sleep (n=273,269,218,221,206,203,160,145)	33.5	34.5	39.4	35.2
Decr sleep (n=263,255,218,223,205,190,151,129)	30.2	25.8	27.2	27.1
Med-treat sx (n=267,256,232,243,216,209,176,163)	55.6	55.5	59.7	60.1
Med-prevent sx (n=269,258,231,237,222,211,178,159)	56.3	53.6	59.6	61.6

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Antibody Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in 13vPnC Group After the Second Dose and After the Third Dose of a 3-Dose Infant Series and After the Toddler Dose

End point title	Geometric Mean Antibody Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in 13vPnC Group After the Second Dose and After the Third Dose of a 3-Dose Infant Series and After the Toddler Dose
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End point description:

GMC as measured by enzyme-linked immunosorbent assay (ELISA) for 7 common pneumococcal serotypes which are present in both 7vPnC and 13vPnC (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. The evaluable immunogenicity (per protocol) population was the primary analysis 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 IgG antibody concentration to the given serotype.

End point type	Primary
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End point timeframe:

One month after infant series dose 2 (at 5 months of age) and dose 3 (at 7 months of age) and one month after the toddler dose (at 16 months of age)

End point values	13vPnC After Infant Series Dose 2	13vPnC After Infant Series Dose 3	13vPnC After the Toddler Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	297	293	275	
Units: microgram per millilitre (mcg/mL)				
geometric mean (confidence interval 95%)				
Common Serotype - Serotype 4 (n=269,269,241)	1.89 (1.7 to 2.1)	2.33 (2.11 to 2.57)	4.97 (4.42 to 5.58)	
Common Serotype - Serotype 6B (n=267,267,228)	0.42 (0.37 to 0.47)	3.88 (3.41 to 4.41)	11.88 (10.57 to 13.35)	
Common Serotype - Serotype 9V (n=273,273,241)	1.49 (1.34 to 1.66)	1.71 (1.56 to 1.86)	3.44 (3.12 to 3.8)	
Common Serotype - Serotype 14 (n=270,270,230)	3.84 (3.37 to 4.37)	6.17 (5.45 to 6.98)	11.37 (10.17 to 12.71)	
Common Serotype - Serotype 18C (n=267,267,239)	1.58 (1.4 to 1.78)	2.29 (2.08 to 2.52)	3.96 (3.55 to 4.43)	
Common Serotype - Serotype 19F (n=270,270,231)	2.85 (2.53 to 3.21)	2.64 (2.42 to 2.89)	8.04 (7.07 to 9.14)	
Common Serotype - Serotype 23F (n=260,260,233)	0.54 (0.47 to 0.62)	2.15 (1.89 to 2.45)	5.07 (4.5 to 5.71)	
Additional Serotype - Serotype 1 (n=268,268,235)	1.9 (1.7 to 2.13)	3.04 (2.73 to 3.38)	4.79 (4.21 to 5.45)	
Additional Serotype - Serotype 3 (n=267,267,243)	0.79 (0.72 to 0.87)	0.97 (0.87 to 1.08)	1.07 (0.95 to 1.2)	
Additional Serotype - Serotype 5 (n=261,261,234)	0.99 (0.9 to 1.1)	1.93 (1.74 to 2.13)	3.9 (3.53 to 4.31)	
Additional Serotype - Serotype 6A (n=269,269,235)	1.1 (0.97 to 1.25)	3.16 (2.82 to 3.53)	7.07 (6.35 to 7.87)	
Additional Serotype - Serotype 7F (n=268,268,242)	1.85 (1.69 to 2.02)	4.03 (3.7 to 4.4)	5.78 (5.13 to 6.53)	
Additional Serotype - Serotype 19A (n=267,267,226)	2.36 (2.1 to 2.66)	3.07 (2.79 to 3.37)	11.64 (10.43 to 13)	

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description:	
The Geometric Mean fold Rise (GMFR) were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.35

Statistical analysis title	Serotype 6B
Statistical analysis description: The difference in percentages between the two groups (13vPnC - 7vPnC) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	9.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.18
upper limit	10.53

Statistical analysis title	Serotype 9V
Statistical analysis description: The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	1.25

Statistical analysis title	Serotype 14
Statistical analysis description: The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3

Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.41
upper limit	1.83

Statistical analysis title	Serotype 18C
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Statistical analysis description:

The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	1.61

Statistical analysis title	Serotype 19F
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Statistical analysis description:

The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.

Comparison groups	13vPnC After Infant Series Dose 3 v 13vPnC After Infant Series Dose 2
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.03

Statistical analysis title	Serotype 23F
Statistical analysis description: The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	4
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.55
upper limit	4.5

Statistical analysis title	Serotype 1
Statistical analysis description: The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	1.76

Statistical analysis title	Serotype 3
Statistical analysis description: The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.23

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.35

Statistical analysis title	Serotype 5
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Statistical analysis description:

The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	2.11

Statistical analysis title	Serotype 6A
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Statistical analysis description:

The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	2.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.58
upper limit	3.2

Statistical analysis title	Serotype 7F
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Statistical analysis description:

The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
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Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	2.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.98
upper limit	2.41

Statistical analysis title	Serotype 19A
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Statistical analysis description:

The GMFR were calculated using all subjects with available data from both 13vPnC After Infant Series Dose 2 and 13vPnC After Infant Series Dose 3 blood draws.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.18
upper limit	1.44

Primary: Percentage of Subjects Achieving Predefined Antibody Levels for Pertussis, Diphtheria, Tetanus, and Poliovirus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose

End point title	Percentage of Subjects Achieving Predefined Antibody Levels for Pertussis, Diphtheria, Tetanus, and Poliovirus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose
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End point description:

Percentage of subjects achieving predefined antibody threshold levels with the corresponding 95 % CI for each concomitant antigen (pertussis antigens including Pertussis Toxoid (PT), Filamentous Haemagglutinin (FHA), and Pertactin (PRN); diphtheria; tetanus; and poliovirus types 1, 2, and 3) are presented. The evaluable immunogenicity (per protocol) population was the primary analysis 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
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End point timeframe:

One month after the 3-dose infant series (7 months of age) and the toddler dose (16 months of age)

End point values	13vPnC After Infant Series	7vPnC After Infant Series	13vPnC After the Toddler Dose	7vPnC After the Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	293	286	275	270
Units: percentage of subjects				
number (confidence interval 95%)				
Pertussis, PT $\geq$ 5.0 EU/mL	100 (98.7 to 100)	100 (98.7 to 100)	99.6 (98 to 100)	99.6 (97.9 to 100)
Pertussis, PT (Infant $\geq$ 20; Toddler $\geq$ 11) EU/mL	93.2 (89.7 to 95.8)	95.1 (91.9 to 97.3)	94.9 (91.6 to 97.2)	96.3 (93.3 to 98.2)
Pertussis, FHA $\geq$ 5.0 EU/mL	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.6 to 100)
Pertussis, FHA $\geq$ 7.82 EU/mL	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.6 to 100)
Pertussis, FHA (Infant $\geq$ 64; Toddler $\geq$ 99) EU/mL	93.9 (90.5 to 96.3)	95.1 (91.9 to 97.3)	94.5 (91.1 to 96.9)	95.1 (91.8 to 97.4)
Pertussis, PRN $\geq$ 5 EU/mL	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.6 to 100)
Pertussis, PRN (Infant $\geq$ 39; Toddler $\geq$ 69) EU/mL	94.5 (91.3 to 96.8)	95.1 (91.9 to 97.3)	93.5 (89.9 to 96.1)	95.2 (91.9 to 97.4)
Diphtheria $\geq$ 0.10 IU/mL	99.3 (97.5 to 99.9)	100 (98.7 to 100)	99.2 (97.2 to 99.9)	100 (98.5 to 100)
Diphtheria $\geq$ 0.01 IU/mL	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.6 to 100)	100 (98.5 to 100)
Tetanus $\geq$ 0.10 IU/mL	98.6 (96.3 to 99.6)	98.2 (95.8 to 99.4)	98.6 (95.9 to 99.7)	97.8 (94.9 to 99.3)
Tetanus $\geq$ 0.01 IU/mL	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.3 to 100)	100 (98.4 to 100)
Poliovirus, Type 1 $\geq$ 1:8	100 (98.7 to 100)	100 (98.7 to 100)	100 (98.6 to 100)	100 (98.6 to 100)
Poliovirus, Type 2 $\geq$ 1:8	100 (98.7 to 100)	99.3 (97.5 to 99.9)	100 (98.6 to 100)	99.6 (97.8 to 100)
Poliovirus, Type 3 $\geq$ 1:8	100 (98.7 to 100)	99.6 (98 to 100)	100 (98.6 to 100)	100 (98.6 to 100)

Statistical analyses

Statistical analysis title	Pertussis, PT $\geq$ 5.0 EU/mL: After Infant Series
Statistical analysis description:	
For Pertussis, PT the difference in percentage between the two groups (13vPnC - 7vPnC) at 5.0 enzyme-linked immunosorbent assay (ELISA) unit (EU)/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

Statistical analysis title	Pertussis, PT ≥ 20 EU/mL: After Infant Series
Statistical analysis description: For Pertussis, PT the difference in percentage between the two groups (13vPnC - 7vPnC) at 20 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $> -10\%$.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	2

Statistical analysis title	Pertussis, FHA ≥ 5.0 EU/mL: After Infant Series
Statistical analysis description: For Pertussis, FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 5.0 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $> -10\%$.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

Statistical analysis title	Pertussis, FHA ≥ 7.82 EU/mL: After Infant Series
Statistical analysis description: For Pertussis, FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 7.82 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $> -10\%$.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series

Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

Statistical analysis title	Pertussis, FHA $\geq$ 64 EU/mL: After Infant Series
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Statistical analysis description:

For Pertussis, FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 64 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	2.6

Statistical analysis title	Pertussis, PRN $\geq$ 5 EU/mL: After Infant Series
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Statistical analysis description:

For Pertussis, PRN the difference in percentage between the two groups (13vPnC - 7vPnC) at 5 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

Statistical analysis title	Pertussis, PRN $\geq$ 39 EU/mL: After Infant Series
Statistical analysis description:	
For Pertussis, PRN the difference in percentage between the two groups (13vPnC - 7vPnC) at 39 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	3.2

Statistical analysis title	Pertussis, PT $\geq$ 5.0 EU/mL: After Toddler Series
Statistical analysis description:	
For Pertussis, PT the difference in percentage between the two groups (13vPnC - 7vPnC) at 5.0 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	1.7

Statistical analysis title	Pertussis, PT $\geq$ 11 EU/mL: After Toddler Series
Statistical analysis description:	
For Pertussis, PT the difference in percentage between the two groups (13vPnC - 7vPnC) at 11 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-1.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	2.2

Statistical analysis title	Pertussis, FHA $\geq$ 5.0 EU/mL: After Toddler dose
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Statistical analysis description:

For Pertussis, FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 5.0 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Statistical analysis title	Pertussis, FHA $\geq$ 7.82 EU/mL: After Toddler dose
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Statistical analysis description:

For Pertussis, FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 7.82 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Statistical analysis title	Pertussis, FHA $\geq$ 99 EU/mL: After Toddler dose
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Statistical analysis description:

For Pertussis, FHA the difference in percentage between the two groups (13vPnC - 7vPnC) at 99 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	3.3

Statistical analysis title	Pertussis, PRN $\geq$ 5 EU/mL: After Toddler dose
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Statistical analysis description:

For Pertussis, PRN the difference in percentage between the two groups (13vPnC - 7vPnC) at 5 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Statistical analysis title	Pertussis, PRN $\geq$ 69 EU/mL: After Toddler dose
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Statistical analysis description:

For Pertussis, PRN the difference in percentage between the two groups (13vPnC - 7vPnC) at 69 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	2.3

Statistical analysis title	Diphtheria $\geq$ 0.01 IU/mL: After Infant Series
Statistical analysis description: For Diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	1.3

Statistical analysis title	Diphtheria $\geq$ 0.10 IU/mL: After Infant Series
Statistical analysis description: For Diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.10 International Units (IU)/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	0.7

Statistical analysis title	Diphtheria $\geq$ 0.10 IU/mL: After Toddler dose
Statistical analysis description: For Diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.10 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose

Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	0.8

Statistical analysis title	Diphtheria $\geq$ 0.01 IU/mL: After Toddler dose
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Statistical analysis description:

For Diphtheria the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	1.5

Statistical analysis title	Tetanus $\geq$ 0.10 IU/mL : After Infant Series
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Statistical analysis description:

For Tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.10 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.9

Statistical analysis title	Tetanus >= 0.01 IU/mL: After Infant Series
Statistical analysis description:	
For Tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.	
Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.4

Statistical analysis title	Tetanus >= 0.10 IU/mL: After Toddler dose
Statistical analysis description:	
For Tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.10 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	3.8

Statistical analysis title	Tetanus >= 0.01 IU/mL: After Toddler dose
Statistical analysis description:	
For Tetanus the difference in percentage between the two groups (13vPnC - 7vPnC) at 0.01 IU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	1.7

Statistical analysis title	Poliovirus, Type 1 $\geq$ 1:8: After Infant Series
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Statistical analysis description:

For Poliovirus Type 1 the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.3

Statistical analysis title	Poliovirus, Type 2 $\geq$ 1:8: After Infant Series
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Statistical analysis description:

For Poliovirus Type 2 the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	2.6

Statistical analysis title	Poliovirus, Type 3 $\geq$ 1:8: After Infant Series
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Statistical analysis description:

For Poliovirus Type 3 the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After Infant Series v 7vPnC After Infant Series
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	2

Statistical analysis title	Poliovirus, Type 2 $\geq$ 1:8: After Toddler dose
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Statistical analysis description:

For Poliovirus Type 2 the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	2.2

Statistical analysis title	Poliovirus, Type 1 $\geq$ 1:8: After Toddler dose
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Statistical analysis description:

For Poliovirus Type 1 the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) $>$ -10%.

Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	1.5

Statistical analysis title	Poliovirus, Type 3 >= 1:8: After Toddler dose
Statistical analysis description: For Poliovirus Type 3 the difference in percentage between the two groups (13vPnC - 7vPnC) at 1:8 EU/mL threshold was calculated. Non-inferiority for concomitant antigens was declared if the lowest limit of 2-sided 95% CI for the difference between the 2 groups (13vPnC - 7vPnC) > -10%.	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	1.5

Primary: Geometric Mean Titers (GMT) for Poliovirus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose

End point title	Geometric Mean Titers (GMT) for Poliovirus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose
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End point description:

The evaluable immunogenicity (per protocol) population was the primary analysis 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
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End point timeframe:

One month after the 3-dose infant series (7 months of age) and the toddler dose (16 months of age)

End point values	13vPnC After Infant Series Dose 3	7vPnC After Infant Series Dose 3	13vPnC After the Toddler Dose	7vPnC Afte the Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	293	286	275	270
Units: titer				
geometric mean (confidence interval 95%)				
Poliovirus Type 1	436.98 (378.21 to 504.88)	436.15 (378.17 to 503.02)	1057.4 (939.06 to 1190.7)	1286.7 (1131 to 1463.8)
Poliovirus Type 2	266.34 (227.84 to 311.36)	281.85 (240.04 to 330.94)	1032.3 (912.96 to 1167.1)	1141.1 (992.96 to 1311.4)
Poliovirus Type 3	897.67 (766.3 to 1051.6)	943.95 (806.71 to 1104.5)	2571.1 (2249.4 to 2938.9)	2410.8 (2106.7 to 2758.8)

Statistical analyses

Statistical analysis title	Poliovirus Type 1: After Infant Series Dose 3
Statistical analysis description: For Poliovirus Type 1 the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).	
Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.23

Statistical analysis title	Poliovirus Type 2: After Infant Series Dose 3
Statistical analysis description: For Poliovirus Type 2 the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).	
Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.18

Statistical analysis title	Poliovirus Type 3: After Infant Series Dose 3
Statistical analysis description: For Poliovirus Type 3 the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC	

group/7vPnC group) was >0.5 (2-fold criterion).

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.19

Statistical analysis title

Poliovirus Type 1: After Toddler Dose

Statistical analysis description:

For Poliovirus Type 1 the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Comparison groups	7vPnC After the Toddler Dose v 13vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.98

Statistical analysis title

Poliovirus Type 2: After Toddler dose

Statistical analysis description:

For Poliovirus Type 2 the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).

Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.09

Statistical analysis title	Poliovirus Type 3: After Toddler dose
Statistical analysis description: For Poliovirus Type 3 the GMT ratio (13vPnC/7vPnC) was calculated. Non-inferiority for concomitant antigens was declared if the lower bound of the 2-sided, 95% CI for the GMT ratio (13vPnC group/7vPnC group) was >0.5 (2-fold criterion).	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC Afte the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.29

Primary: Geometric Mean Antibody Concentrations (GMC) for Diphtheria and Tetanus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose

End point title	Geometric Mean Antibody Concentrations (GMC) for Diphtheria and Tetanus in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose
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End point description:

The evaluable immunogenicity (per protocol) population was the primary analysis 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
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End point timeframe:

One month after the 3-dose infant series (7 months of age) and the toddler dose (16 months of age)

End point values	13vPnC After Infant Series Dose 3	7vPnC After Infant Series Dose 3	13vPnC After the Toddler Dose	7vPnC Afte the Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	293	286	275	270
Units: IU/mL				
geometric mean (confidence interval 95%)				
Diphtheria	1.19 (1.08 to 1.3)	1.4 (1.28 to 1.53)	3 (2.65 to 3.4)	3.51 (3.08 to 3.99)
Tetanus	0.9 (0.8 to 1.01)	0.87 (0.79 to 0.97)	1.63 (1.38 to 1.91)	1.45 (1.24 to 1.69)

Statistical analyses

Statistical analysis title	Diphtheria: After Infant Series Dose 3
Statistical analysis description: For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.96

Statistical analysis title	Tetanus: After Infant Series Dose 3
Statistical analysis description: For Tetanus the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.2

Statistical analysis title	Diphtheria: After Toddler dose
Statistical analysis description: For diphtheria toxoid the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose

Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.02

Statistical analysis title	Tetanus: After Toddler dose
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Statistical analysis description:

For Tetanus the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).

Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.4

Primary: Geometric Mean Antibody Concentrations (GMC) for Pertussis in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose

End point title	Geometric Mean Antibody Concentrations (GMC) for Pertussis in 13vPnC Group Relative to 7vPnC Group After the 3-dose Infant Series and the Toddler Dose
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End point description:

GMCs with the corresponding 95% CI for each concomitant antigen pertussis antigens (PT, FHA, PRN, and FIM) as measured by EU/mL are presented. The evaluable immunogenicity (per protocol) population was the primary analysis 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
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End point timeframe:

One month after the 3-dose infant series (7 months of age) and the toddler dose (16 months of age)

End point values	13vPnC After Infant Series Dose 3	7vPnC After Infant Series Dose 3	13vPnC After the Toddler Dose	7vPnC After the Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	293	286	275	270
Units: EU/mL				
geometric mean (confidence interval 95%)				
Pertussis PT	51.51 (47.94 to 55.34)	50.13 (46.8 to 53.7)	36.13 (32.84 to 39.74)	36.01 (32.94 to 39.37)
Pertussis FHA	179.04 (165.34 to 193.87)	166.77 (155.2 to 179.2)	347.96 (316.46 to 382.59)	345.89 (315.14 to 379.65)
Pertussis PRN	141.39 (129.66 to 154.17)	135.06 (123.56 to 147.63)	232.96 (211.42 to 256.69)	261.58 (237.29 to 288.36)

Statistical analyses

Statistical analysis title	Pertussis PT: After Infant Series Dose 3
Statistical analysis description:	
For Pertussis PT the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.13

Statistical analysis title	Pertussis FHA: After Infant Series Dose 3
Statistical analysis description:	
For Pertussis FHA the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3

Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.2

Statistical analysis title	Pertussis PRN: After Infant Series Dose 3
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Statistical analysis description:

For Pertussis PRN the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).

Comparison groups	13vPnC After Infant Series Dose 3 v 7vPnC After Infant Series Dose 3
Number of subjects included in analysis	579
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.18

Statistical analysis title	Pertussis FHA: After Toddler dose
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Statistical analysis description:

For Pertussis FHA the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).

Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.15

Statistical analysis title	Pertussis PT: After Toddler dose
Statistical analysis description:	
For Pertussis PT the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.14

Statistical analysis title	Pertussis PRN: After Toddler dose
Statistical analysis description:	
For Pertussis PRN the GMC ratio (13vPnC/7vPnC) was calculated. Non-inferiority for 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).	
Comparison groups	13vPnC After the Toddler Dose v 7vPnC After the Toddler Dose
Number of subjects included in analysis	545
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.02

Primary: Percentage of Subjects Achieving Antibody Level $\geq$ 0.35 mcg/mL in 13vPnC Group After the Second Dose and After the Third Dose of a 3-Dose Infant Series and After the Toddler Dose

End point title	Percentage of Subjects Achieving Antibody Level $\geq$ 0.35 mcg/mL in 13vPnC Group After the Second Dose and After the Third Dose of a 3-Dose Infant Series and After the Toddler Dose
End point description:	
Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold $\geq$ 0.35mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes, present in both 13vPnC and 7vPnC (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. The evaluable immunogenicity (per protocol) population was the primary analysis 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 (at 5 months of age) and dose 3 (at 7 months of age) and one month after the toddler dose (at 16 months of age)

End point values	13vPnC After Infant Series Dose 2	13vPnC After Infant Series Dose 3	13vPnC After the Toddler Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	297	293	275	
Units: Percentage of subjects				
number (confidence interval 95%)				
Common Serotype - Serotype 4	96.7 (93.7 to 98.5)	98.9 (96.8 to 99.8)	99.2 (97 to 99.9)	
Common Serotype - Serotype 6B	57.3 (51.1 to 63.3)	98.5 (96.2 to 99.6)	99.6 (97.6 to 100)	
Common Serotype - Serotype 9V	91.9 (88.1 to 94.9)	99.3 (97.4 to 99.9)	100 (98.5 to 100)	
Common Serotype - Serotype 14	98.5 (96.3 to 99.6)	97.4 (94.7 to 99)	100 (98.4 to 100)	
Common Serotype - Serotype 18C	91.8 (87.8 to 94.8)	98.1 (95.7 to 99.4)	99.6 (97.7 to 100)	
Common Serotype - Serotype 19F	97.8 (95.2 to 99.2)	99.3 (97.3 to 99.9)	99.6 (97.6 to 100)	
Common Serotype - Serotype 23F	68.1 (62 to 73.7)	94.6 (91.1 to 97)	99.1 (96.9 to 99.9)	
Additional Serotype - Serotype 1	96.3 (93.2 to 98.2)	99.3 (97.3 to 99.9)	98.7 (96.3 to 99.7)	
Additional Serotype - Serotype 3	88 (83.5 to 91.7)	90.3 (86.1 to 93.5)	92.2 (88.1 to 95.2)	
Additional Serotype - Serotype 5	87.4 (82.7 to 91.1)	97.3 (94.6 to 98.9)	99.1 (96.9 to 99.9)	
Additional Serotype - Serotype 6A	84.4 (79.5 to 88.5)	97.4 (94.7 to 98.9)	99.1 (97 to 99.9)	
Additional Serotype - Serotype 7F	98.5 (96.2 to 99.6)	100 (98.6 to 100)	98.8 (96.4 to 99.7)	
Additional Serotype - Serotype 19A	98.1 (95.7 to 99.4)	99.6 (97.9 to 100)	100 (98.4 to 100)	

Statistical analyses

Statistical analysis title	Serotype 4
Statistical analysis description: The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3

Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	4.4

Statistical analysis title	Serotype 6B
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	41.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.9
upper limit	46.9

Statistical analysis title	Serotype 9V
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.1
upper limit	10.4

Statistical analysis title	Serotype 14
Statistical analysis description: The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	1.2

Statistical analysis title	Serotype 18C
Statistical analysis description: The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	6.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	9.5

Statistical analysis title	Serotype 19F
Statistical analysis description: The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	1.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	3.4

Statistical analysis title	Serotype 23F
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	26.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.7
upper limit	31.9

Statistical analysis title	Serotype 1
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	5.1

Statistical analysis title	Serotype 3
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
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Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	6.3

Statistical analysis title	Serotype 5
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	10
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.9
upper limit	13.9

Statistical analysis title	Serotype 6A
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Statistical analysis description:

The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.

Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	13
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.6
upper limit	17.2

Statistical analysis title	Serotype 7F
Statistical analysis description: The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	3.1

Statistical analysis title	Serotype 19A
Statistical analysis description: The difference in percentages between the two groups (13vPnC After Infant Series Dose 2 - 13vPnC After Infant Series Dose 3) was calculated.	
Comparison groups	13vPnC After Infant Series Dose 2 v 13vPnC After Infant Series Dose 3
Number of subjects included in analysis	590
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	3.4

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs: recorded from the signing of the ICF to 1 month after infant series and from toddler dose to 1 month after toddler dose. Serious adverse events (SAEs): recorded from the signing of the informed consent to 6 months after the last study vaccination

Adverse event reporting additional description:

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0.0
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Reporting groups

Reporting group title	13vPnC Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with a combination vaccine Infanrix hexa and Meningitec at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months, assessment was done approximately one month after dose 3 at 7 months of age.

Reporting group title	7vPnC Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with a combination vaccine Infanrix hexa and Meningitec at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months, assessment was done approximately one month after dose 3 at 7 months of age.

Reporting group title	13vPnC After Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with a combination vaccine Infanrix hexa and Meningitec at 2 and 4 months. Subjects received 13vPnC coadministered with Infanrix hexa at 6 months, assessment was done at 15 months (toddler dose) to summarize AE/SAE between approximately one month after dose 3 at 7 months of age and toddler dose at 15 month of age.

Reporting group title	7vPnC After Infant Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with a combination vaccine Infanrix hexa and Meningitec at 2 and 4 months. Subjects received 7vPnC coadministered with Infanrix hexa at 6 months, assessment was done at 15 months (toddler dose) to summarize AE/SAE between approximately one month after dose 3 at 7 months of age and toddler dose at 15 month of age.

Reporting group title	13vPnC Toddler Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 13vPnC coadministered with MMR II at 12 months. Subjects received one single 0.5 mL dose of 13vPnC coadministered with Infanrix-IPV+Hib and Meningitec at 15 months (toddler dose). Assessment was done approximately one month after toddler dose at 16 months of age.

Reporting group title	7vPnC Toddler Series
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Reporting group description:

Subjects received one single 0.5 mL dose of 7vPnC coadministered with MMR II at 12 months. Subjects received one single 0.5 mL dose of 7vPnC coadministered with Infanrix-IPV+Hib and Meningitec at 15 months (toddler dose). Assessment was done approximately one month after toddler dose at 16 months of age.

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

Assessment was done approximately 6 months after 13vPnC toddler dose at 21 months of age.

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

Assessment was done approximately 6 months after 7vPnC toddler dose at 21 months of age.

Serious adverse events	13vPnC Infant Series	7vPnC Infant Series	13vPnC After Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 314 (5.10%)	16 / 300 (5.33%)	9 / 314 (2.87%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (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
Skull fracture			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (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
Thermal burn			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital nystagmus			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (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
Scaphocephaly			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fontanelle bulging			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (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
Hypotonia			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 314 (0.32%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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			
Oral disorder			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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
Diarrhoea			

subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
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			
Agitation			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 314 (0.32%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	2 / 314 (0.64%)	1 / 300 (0.33%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			

subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (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
Lobar pneumonia			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (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
Tuberculosis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			

subjects affected / exposed	6 / 314 (1.91%)	6 / 300 (2.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	4 / 314 (1.27%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 314 (0.00%)	4 / 300 (1.33%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (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
Viral infection			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (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
Infected cyst			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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 tract infection			

subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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
Diabetes mellitus			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (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	9 / 300 (3.00%)	3 / 291 (1.03%)	1 / 284 (0.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			

subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital nystagmus			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scaphocephaly			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fontanelle bulging			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Oral disorder			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Agitation			

subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	2 / 300 (0.67%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis rotavirus			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected cyst			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	1 / 284 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			

subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC 6-Month Follow-up	7vPnC 6-Month Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 312 (0.96%)	6 / 299 (2.01%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Congenital nystagmus			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scaphocephaly			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Febrile convulsion			

subjects affected / exposed	0 / 312 (0.00%)	2 / 299 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fontanelle bulging			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden infant death syndrome			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Oral disorder			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diarrhoea			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (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	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (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			
Gastroenteritis			
subjects affected / exposed	2 / 312 (0.64%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			

subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobar pneumonia			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epstein-Barr virus infection			
subjects affected / exposed	1 / 312 (0.32%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			

subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected cyst			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (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	254 / 314 (80.89%)	226 / 300 (75.33%)	7 / 314 (2.23%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	20 / 314 (6.37%)	16 / 300 (5.33%)	0 / 314 (0.00%)
occurrences (all)	23	18	0
Injection site swelling			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Irritability			

subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	4 / 300 (1.33%) 4	0 / 314 (0.00%) 0
Cyst subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 2	0 / 314 (0.00%) 0
Hypothermia subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Injection site reaction subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Fever >=38 degree C but <=39 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all)	80 / 262 (30.53%) 80	62 / 253 (24.51%) 62	0 / 314 (0.00%) 0
Fever >39 degree C but <=40 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	2 / 249 (0.80%) 2	2 / 247 (0.81%) 2	0 / 314 (0.00%) 0
Fever >40 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	0 / 249 (0.00%) 0	0 / 247 (0.00%) 0	0 / 314 (0.00%) 0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	107 / 269 (39.78%) 107	95 / 258 (36.82%) 95	0 / 314 (0.00%) 0
Irritability Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
142 / 276 (51.45%) 142	114 / 267 (42.70%) 114	0 / 314 (0.00%) 0	
Increased sleep Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
146 / 273 (53.48%) 146	138 / 269 (51.30%) 138	0 / 314 (0.00%) 0	
Decreased sleep Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
91 / 263 (34.60%) 91	63 / 255 (24.71%) 63	0 / 314 (0.00%) 0	
Fever >=38 degree C but <=39 degree C Infant Series Dose 2 alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
86 / 213 (40.38%) 86	93 / 223 (41.70%) 93	0 / 314 (0.00%) 0	
Fever >39 degree C but <=40 degree C Infant Series Dose 2 alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
5 / 194 (2.58%) 5	5 / 204 (2.45%) 5	0 / 314 (0.00%) 0	
Decreased appetite Infant Series Dose 2 alternative dictionary used:	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[10]	102 / 226 (45.13%)	102 / 229 (44.54%)	0 / 314 (0.00%)
occurrences (all)	102	102	0
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[11]	151 / 234 (64.53%)	150 / 244 (61.48%)	0 / 314 (0.00%)
occurrences (all)	151	150	0
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[12]	102 / 218 (46.79%)	92 / 221 (41.63%)	0 / 314 (0.00%)
occurrences (all)	102	92	0
Decreased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[13]	79 / 218 (36.24%)	66 / 223 (29.60%)	0 / 314 (0.00%)
occurrences (all)	79	66	0
Fever >=38 degree C but <=39 degree C Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[14]	68 / 198 (34.34%)	75 / 196 (38.27%)	0 / 314 (0.00%)
occurrences (all)	68	75	0
Fever >39 degree C but <=40 degree C Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[15]	10 / 177 (5.65%)	9 / 174 (5.17%)	0 / 314 (0.00%)
occurrences (all)	10	9	0
Irritability Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	131 / 229 (57.21%) 131	130 / 221 (58.82%) 130	0 / 314 (0.00%) 0
Increased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	69 / 206 (33.50%) 69	70 / 203 (34.48%) 70	0 / 314 (0.00%) 0
Decreased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	62 / 205 (30.24%) 62	49 / 190 (25.79%) 49	0 / 314 (0.00%) 0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	2 / 314 (0.64%)
occurrences (all)	0	0	2
Milk allergy			
subjects affected / exposed	0 / 314 (0.00%)	2 / 300 (0.67%)	1 / 314 (0.32%)
occurrences (all)	0	2	1
Social circumstances			
Exposure to communicable disease			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Penis disorder			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Testicular retraction			

subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	1 / 314 (0.32%)	1 / 300 (0.33%)	1 / 314 (0.32%)
occurrences (all)	1	1	1
Asthma			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	1 / 314 (0.32%)
occurrences (all)	1	0	1
Cough			
subjects affected / exposed	7 / 314 (2.23%)	4 / 300 (1.33%)	0 / 314 (0.00%)
occurrences (all)	7	4	0
Rhinorrhoea			
subjects affected / exposed	0 / 314 (0.00%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	0	2	0
Bronchitis chronic			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	2	0	0
Respiratory failure			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Agitation			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Investigations			

Weight decreased subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Injury, poisoning and procedural complications			
Traumatic brain injury subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Overdose subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Head injury subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Congenital, familial and genetic disorders			
Hip dysplasia subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	2 / 300 (0.67%) 2	0 / 314 (0.00%) 0
Atrial septal defect subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Double ureter subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Hydrocele subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Hypospadias subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Strabismus congenital subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Nervous system disorders			
Febrile convulsion subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0

Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	10 / 314 (3.18%)	10 / 300 (3.33%)	0 / 314 (0.00%)
occurrences (all)	12	11	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 314 (0.00%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Coeliac disease			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	11 / 314 (3.50%)	5 / 300 (1.67%)	1 / 314 (0.32%)
occurrences (all)	12	5	1
Vomiting			
subjects affected / exposed	7 / 314 (2.23%)	4 / 300 (1.33%)	0 / 314 (0.00%)
occurrences (all)	7	4	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 314 (0.64%)	4 / 300 (1.33%)	0 / 314 (0.00%)
occurrences (all)	24	4	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 314 (0.96%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	3	0	0
Abdominal pain			

subjects affected / exposed	1 / 314 (0.32%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	1	1	0
Stomatitis			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[19]	103 / 219 (47.03%)	87 / 204 (42.65%)	0 / 314 (0.00%)
occurrences (all)	103	87	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	6 / 314 (1.91%)	9 / 300 (3.00%)	0 / 314 (0.00%)
occurrences (all)	6	9	0
Dermatitis diaper			
subjects affected / exposed	2 / 314 (0.64%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	1 / 314 (0.32%)	4 / 300 (1.33%)	0 / 314 (0.00%)
occurrences (all)	1	4	0
Urticaria			
subjects affected / exposed	0 / 314 (0.00%)	3 / 300 (1.00%)	0 / 314 (0.00%)
occurrences (all)	0	4	0
Rash generalised			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 314 (0.00%)	3 / 300 (1.00%)	0 / 314 (0.00%)
occurrences (all)	0	3	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 314 (0.32%)	4 / 300 (1.33%)	0 / 314 (0.00%)
occurrences (all)	1	4	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			

alternative assessment type: Systematic subjects affected / exposed^[20] occurrences (all)	136 / 275 (49.45%)	117 / 270 (43.33%)	0 / 314 (0.00%)
	136	117	0
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[21] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	7 / 247 (2.83%)	7 / 250 (2.80%)	0 / 314 (0.00%)
	7	7	0
Induration (Any) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[22] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	48 / 252 (19.05%)	36 / 254 (14.17%)	0 / 314 (0.00%)
	48	36	0
Induration (Mild) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[23] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	41 / 251 (16.33%)	36 / 254 (14.17%)	0 / 314 (0.00%)
	41	36	0
Induration (Moderate) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[24] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	12 / 247 (4.86%)	4 / 248 (1.61%)	0 / 314 (0.00%)
	12	4	0
Erythema (Any) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[25] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	56 / 255 (21.96%)	48 / 251 (19.12%)	0 / 314 (0.00%)
	56	48	0
Erythema (Mild) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative assessment type: Systematic subjects affected / exposed^[26] occurrences (all)	51 / 254 (20.08%)	46 / 251 (18.33%)	0 / 314 (0.00%)
51 46 0			
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[27] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
6 / 247 (2.43%) 3 / 247 (1.21%) 0 / 314 (0.00%)			
6 3 0			
Tenderness (Any) Infant Series Dose 2 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[28] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
103 / 227 (45.37%) 108 / 232 (46.55%) 0 / 314 (0.00%)			
103 108 0			
Tenderness (Significant) Infant Series Dose 2 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[29] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
8 / 192 (4.17%) 8 / 203 (3.94%) 0 / 314 (0.00%)			
8 8 0			
Induration (Any) Infant Series Dose 2 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[30] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
58 / 206 (28.16%) 49 / 212 (23.11%) 0 / 314 (0.00%)			
58 49 0			
Induration (Mild) Infant Series Dose 2 alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed^[31] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
53 / 206 (25.73%) 43 / 212 (20.28%) 0 / 314 (0.00%)			
53 43 0			
Induration (Moderate) Infant Series Dose 2 alternative dictionary used: Local Reaction 0.0	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative assessment type: Systematic subjects affected / exposed ^[32] occurrences (all)	11 / 191 (5.76%) 11	9 / 201 (4.48%) 9	0 / 314 (0.00%) 0
Erythema (Any) Infant Series Dose 2 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[33] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
 72 / 211 (34.12%) 72	67 / 217 (30.88%) 67	0 / 314 (0.00%) 0	
Erythema (Mild) Infant Series Dose 2 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[34] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
 68 / 210 (32.38%) 68	65 / 215 (30.23%) 65	0 / 314 (0.00%) 0	
Erythema (Moderate) Infant Series Dose 2 alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[35] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
 6 / 192 (3.13%) 6	5 / 203 (2.46%) 5	0 / 314 (0.00%) 0	
Tenderness (Any) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[36] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
 104 / 217 (47.93%) 104	90 / 215 (41.86%) 90	0 / 314 (0.00%) 0	
Tenderness (Significant) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[37] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
 11 / 181 (6.08%) 11	0 / 171 (0.00%) 0	0 / 314 (0.00%) 0	
Induration (Any) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative assessment type: Systematic subjects affected / exposed^[38] occurrences (all)	56 / 203 (27.59%)	53 / 188 (28.19%)	0 / 314 (0.00%)
Induration (Mild) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[39] occurrences (all)	53 / 201 (26.37%)	48 / 186 (25.81%)	0 / 314 (0.00%)
Induration (Moderate) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[40] occurrences (all)	10 / 180 (5.56%)	7 / 173 (4.05%)	0 / 314 (0.00%)
Erythema (Any) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[41] occurrences (all)	63 / 203 (31.03%)	69 / 198 (34.85%)	0 / 314 (0.00%)
Erythema (Mild) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[42] occurrences (all)	59 / 203 (29.06%)	65 / 195 (33.33%)	0 / 314 (0.00%)
Erythema (Moderate) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[43] occurrences (all)	8 / 177 (4.52%)	9 / 175 (5.14%)	0 / 314 (0.00%)
Renal and urinary disorders			

Pyelocaliectasis subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Torticollis subjects affected / exposed occurrences (all)	1 / 314 (0.32%) 1	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Infections and infestations			
Tuberculosis subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	0 / 300 (0.00%) 0	0 / 314 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	25 / 314 (7.96%) 34	23 / 300 (7.67%) 32	0 / 314 (0.00%) 0
Bronchopneumonia subjects affected / exposed occurrences (all)	0 / 314 (0.00%) 0	1 / 300 (0.33%) 1	1 / 314 (0.32%) 1
Ear infection subjects affected / exposed occurrences (all)	8 / 314 (2.55%) 8	6 / 300 (2.00%) 9	0 / 314 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	23 / 314 (7.32%) 26	33 / 300 (11.00%) 35	0 / 314 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	3 / 314 (0.96%) 3	4 / 300 (1.33%) 6	0 / 314 (0.00%) 0
Varicella subjects affected / exposed occurrences (all)	3 / 314 (0.96%) 3	1 / 300 (0.33%) 1	0 / 314 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	19 / 314 (6.05%) 19	22 / 300 (7.33%) 23	0 / 314 (0.00%) 0
Upper respiratory tract infection			

subjects affected / exposed	53 / 314 (16.88%)	47 / 300 (15.67%)	0 / 314 (0.00%)
occurrences (all)	86	67	0
Pharyngitis			
subjects affected / exposed	5 / 314 (1.59%)	7 / 300 (2.33%)	0 / 314 (0.00%)
occurrences (all)	6	10	0
Respiratory tract infection			
subjects affected / exposed	9 / 314 (2.87%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	10	4	0
Otitis media			
subjects affected / exposed	3 / 314 (0.96%)	6 / 300 (2.00%)	0 / 314 (0.00%)
occurrences (all)	3	9	0
Laryngitis			
subjects affected / exposed	1 / 314 (0.32%)	3 / 300 (1.00%)	0 / 314 (0.00%)
occurrences (all)	1	3	0
Otitis media acute			
subjects affected / exposed	4 / 314 (1.27%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	4	1	0
Bronchiolitis			
subjects affected / exposed	32 / 314 (10.19%)	35 / 300 (11.67%)	0 / 314 (0.00%)
occurrences (all)	35	39	0
Acute tonsillitis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	3 / 314 (0.96%)	3 / 300 (1.00%)	0 / 314 (0.00%)
occurrences (all)	3	3	0
Coxsackie viral infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Viral infection			

subjects affected / exposed	2 / 314 (0.64%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	2	1	0
Dacryocystitis			
subjects affected / exposed	3 / 314 (0.96%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	4	2	0
Urinary tract infection			
subjects affected / exposed	3 / 314 (0.96%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	4	2	0
Gastroenteritis rotavirus			
subjects affected / exposed	2 / 314 (0.64%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	2	2	0
Oral candidiasis			
subjects affected / exposed	3 / 314 (0.96%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	3	1	0
Candidiasis			
subjects affected / exposed	2 / 314 (0.64%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	3	1	0
Viral skin infection			
subjects affected / exposed	1 / 314 (0.32%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	1	2	0
Influenza			
subjects affected / exposed	2 / 314 (0.64%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	2	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 314 (0.00%)	2 / 300 (0.67%)	0 / 314 (0.00%)
occurrences (all)	0	2	0
Acarodermatitis			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Herpangina			

subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Skin candida			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	0
Tracheitis			
subjects affected / exposed	1 / 314 (0.32%)	0 / 300 (0.00%)	0 / 314 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 314 (0.00%)	1 / 300 (0.33%)	0 / 314 (0.00%)
occurrences (all)	0	1	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	10 / 300 (3.33%)	170 / 291 (58.42%)	155 / 284 (54.58%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 300 (0.00%)	8 / 291 (2.75%)	4 / 284 (1.41%)
occurrences (all)	0	9	4
Injection site swelling			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Hypothermia			

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Injection site reaction subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Fever >=38 degree C but <=39 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all)	0 / 300 (0.00%) 0	63 / 162 (38.89%) 63	65 / 145 (44.83%) 65
Fever >39 degree C but <=40 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	0 / 300 (0.00%) 0	11 / 135 (8.15%) 11	8 / 118 (6.78%) 8
Fever >40 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	0 / 300 (0.00%) 0	1 / 132 (0.76%) 1	0 / 113 (0.00%) 0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	0 / 300 (0.00%) 0	93 / 174 (53.45%) 93	70 / 147 (47.62%) 70
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			

alternative assessment type: Systematic subjects affected / exposed^[5] occurrences (all)	0 / 300 (0.00%)	113 / 183 (61.75%)	105 / 170 (61.76%)
0 113 105			
Increased sleep Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[6] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
0 / 300 (0.00%) 63 / 160 (39.38%) 51 / 145 (35.17%)			
0 63 51			
Decreased sleep Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[7] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
0 / 300 (0.00%) 41 / 151 (27.15%) 35 / 129 (27.13%)			
0 41 35			
Fever >=38 degree C but <=39 degree C Infant Series Dose 2 alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[8] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
0 / 300 (0.00%) 0 / 291 (0.00%) 0 / 284 (0.00%)			
0 0 0			
Fever >39 degree C but <=40 degree C Infant Series Dose 2 alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[9] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
0 / 300 (0.00%) 0 / 291 (0.00%) 0 / 284 (0.00%)			
0 0 0			
Decreased appetite Infant Series Dose 2 alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[10] occurrences (all)	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
0 / 300 (0.00%) 0 / 291 (0.00%) 0 / 284 (0.00%)			
0 0 0			
Irritability Infant Series Dose 2 alternative dictionary used:	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

Systemic Events 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[11]

occurrences (all)

0 / 300 (0.00%)

0

0 / 291 (0.00%)

0

0 / 284 (0.00%)

0

Increased sleep Infant Series Dose 2

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Events 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[12]

occurrences (all)

0 / 300 (0.00%)

0

0 / 291 (0.00%)

0

0 / 284 (0.00%)

0

Decreased sleep Infant Series Dose 2

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[13]

occurrences (all)

0 / 300 (0.00%)

0

0 / 291 (0.00%)

0

0 / 284 (0.00%)

0

Fever >=38 degree C but <=39 degree C Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[14]

occurrences (all)

0 / 300 (0.00%)

0

0 / 291 (0.00%)

0

0 / 284 (0.00%)

0

Fever >39 degree C but <=40 degree C Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[15]

occurrences (all)

0 / 300 (0.00%)

0

0 / 291 (0.00%)

0

0 / 284 (0.00%)

0

Irritability Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Events 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[16]

occurrences (all)

0 / 300 (0.00%)

0

0 / 291 (0.00%)

0

0 / 284 (0.00%)

0

Increased sleep Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Decreased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Immune system disorders Food allergy subjects affected / exposed occurrences (all) Milk allergy subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0 0 / 300 (0.00%) 0	0 / 291 (0.00%) 0 0 / 291 (0.00%) 0	0 / 284 (0.00%) 0 0 / 284 (0.00%) 0
Social circumstances Exposure to communicable disease subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Reproductive system and breast disorders Genital rash subjects affected / exposed occurrences (all) Penis disorder subjects affected / exposed occurrences (all) Testicular retraction subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1 0 / 300 (0.00%) 0 0 / 300 (0.00%) 0	0 / 291 (0.00%) 0 0 / 291 (0.00%) 0 0 / 291 (0.00%) 0	0 / 284 (0.00%) 0 0 / 284 (0.00%) 0 0 / 284 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchial hyperreactivity subjects affected / exposed occurrences (all) Asthma	1 / 300 (0.33%) 1	3 / 291 (1.03%) 3	1 / 284 (0.35%) 1

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	3 / 291 (1.03%) 3	2 / 284 (0.70%) 2
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	1 / 284 (0.35%) 1
Bronchitis chronic subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	0 / 284 (0.00%) 0
Respiratory failure subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Bronchospasm subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Psychiatric disorders Restlessness subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Agitation subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Investigations Weight decreased subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Injury, poisoning and procedural complications Traumatic brain injury subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Overdose			

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Head injury subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Congenital, familial and genetic disorders			
Hip dysplasia subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Atrial septal defect subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Double ureter subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Hydrocele subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Hypospadias subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Strabismus congenital subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Nervous system disorders			
Febrile convulsion subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Ear and labyrinth disorders			
Otorrhoea subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	1 / 284 (0.35%) 1
Ear pain subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Eye disorders			

Conjunctivitis subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	9 / 291 (3.09%) 9	3 / 284 (1.06%) 3
Dacryostenosis acquired subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Gastrointestinal disorders			
Coeliac disease subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	5 / 291 (1.72%) 7	4 / 284 (1.41%) 4
Vomiting subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	5 / 291 (1.72%) 5	0 / 284 (0.00%) 0
Gastrointestinal inflammation subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	1 / 291 (0.34%) 1	0 / 284 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used:			

Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[19]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Dermatitis diaper			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[20]	0 / 300 (0.00%)	124 / 193 (64.25%)	110 / 170 (64.71%)
occurrences (all)	0	124	110
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[21]	0 / 300 (0.00%)	8 / 136 (5.88%)	8 / 118 (6.78%)
occurrences (all)	0	8	8
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[22]	0 / 300 (0.00%)	51 / 153 (33.33%)	43 / 140 (30.71%)
occurrences (all)	0	51	43
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[23]	0 / 300 (0.00%)	47 / 151 (31.13%)	32 / 132 (24.24%)
occurrences (all)	0	47	32
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[24]	0 / 300 (0.00%)	16 / 136 (11.76%)	16 / 124 (12.90%)
occurrences (all)	0	16	16
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[25]	0 / 300 (0.00%)	65 / 159 (40.88%)	60 / 146 (41.10%)
occurrences (all)	0	65	60
Erythema (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[26]	0 / 300 (0.00%)	55 / 157 (35.03%)	53 / 141 (37.59%)
occurrences (all)	0	55	53
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[27]	0 / 300 (0.00%)	18 / 137 (13.14%)	15 / 120 (12.50%)
occurrences (all)	0	18	15
Tenderness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[28]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[29]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[30]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[31]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[32]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[33]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[34]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Erythema (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[35]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[36]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[37]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[38]	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Induration (Mild) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[39] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Induration (Moderate) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[40] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Erythema (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[41] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Erythema (Mild) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[42] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Erythema (Moderate) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed ^[43] occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Renal and urinary disorders Pyelocaliectasis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Musculoskeletal and connective tissue disorders Torticollis subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Pain in extremity			

subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Infections and infestations			
Tuberculosis			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Bronchitis			
subjects affected / exposed occurrences (all)	2 / 300 (0.67%) 2	11 / 291 (3.78%) 12	16 / 284 (5.63%) 17
Bronchopneumonia			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Ear infection			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	1 / 291 (0.34%) 1	3 / 284 (1.06%) 3
Nasopharyngitis			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	10 / 291 (3.44%) 10	9 / 284 (3.17%) 9
Rhinitis			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Varicella			
subjects affected / exposed occurrences (all)	1 / 300 (0.33%) 1	0 / 291 (0.00%) 0	0 / 284 (0.00%) 0
Gastroenteritis			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	16 / 291 (5.50%) 16	15 / 284 (5.28%) 15
Upper respiratory tract infection			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	15 / 291 (5.15%) 16	12 / 284 (4.23%) 16
Pharyngitis			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	6 / 291 (2.06%) 6	6 / 284 (2.11%) 6
Respiratory tract infection			
subjects affected / exposed occurrences (all)	0 / 300 (0.00%) 0	5 / 291 (1.72%) 5	4 / 284 (1.41%) 5

Otitis media			
subjects affected / exposed	0 / 300 (0.00%)	4 / 291 (1.37%)	5 / 284 (1.76%)
occurrences (all)	0	4	6
Laryngitis			
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)	3 / 284 (1.06%)
occurrences (all)	0	2	3
Otitis media acute			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	3 / 284 (1.06%)
occurrences (all)	0	1	3
Bronchiolitis			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	2 / 284 (0.70%)
occurrences (all)	0	1	2
Acute tonsillitis			
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Pneumonia			
subjects affected / exposed	0 / 300 (0.00%)	3 / 291 (1.03%)	0 / 284 (0.00%)
occurrences (all)	0	3	0
Tonsillitis			
subjects affected / exposed	0 / 300 (0.00%)	2 / 291 (0.69%)	0 / 284 (0.00%)
occurrences (all)	0	2	0
Coxsackie viral infection			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 300 (0.00%)	1 / 291 (0.34%)	0 / 284 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	1 / 284 (0.35%)
occurrences (all)	0	0	1
Dacryocystitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis rotavirus			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Viral skin infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchiolitis			

subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 300 (0.00%)	0 / 291 (0.00%)	0 / 284 (0.00%)
occurrences (all)	0	0	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	3 / 312 (0.96%)	2 / 299 (0.67%)	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Cyst			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Hypothermia			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			

subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (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 SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Fever >39 degree C but <=40 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Fever >40 degree C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			

alternative assessment type: Systematic subjects affected / exposed^[6] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[7] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Fever >=38 degree C but <=39 degree C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[8] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Fever >39 degree C but <=40 degree C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[9] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Decreased appetite Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed^[10] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed^[11] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used:			

Systemic Events 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[12]

occurrences (all)

0 / 312 (0.00%)

0

0 / 299 (0.00%)

0

Decreased sleep Infant Series Dose 2

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[13]

occurrences (all)

0 / 312 (0.00%)

0

0 / 299 (0.00%)

0

Fever >=38 degree C but <=39 degree C Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[14]

occurrences (all)

0 / 312 (0.00%)

0

0 / 299 (0.00%)

0

Fever >39 degree C but <=40 degree C Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[15]

occurrences (all)

0 / 312 (0.00%)

0

0 / 299 (0.00%)

0

Irritability Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Events 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[16]

occurrences (all)

0 / 312 (0.00%)

0

0 / 299 (0.00%)

0

Increased sleep Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used:
Systemic Event 0.0

alternative assessment type:
Systematic

subjects affected / exposed^[17]

occurrences (all)

0 / 312 (0.00%)

0

0 / 299 (0.00%)

0

Decreased sleep Infant Series Dose 3

Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Immune system disorders Food allergy subjects affected / exposed occurrences (all) Milk allergy subjects affected / exposed occurrences (all)	1 / 312 (0.32%) 1 1 / 312 (0.32%) 1	1 / 299 (0.33%) 1 0 / 299 (0.00%) 0	
Social circumstances Exposure to communicable disease subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Reproductive system and breast disorders Genital rash subjects affected / exposed occurrences (all) Penis disorder subjects affected / exposed occurrences (all) Testicular retraction subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0 0 / 312 (0.00%) 0 0 / 312 (0.00%) 0	0 / 299 (0.00%) 0 0 / 299 (0.00%) 0 0 / 299 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Bronchial hyperreactivity subjects affected / exposed occurrences (all) Asthma subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Rhinorrhoea	0 / 312 (0.00%) 0 0 / 312 (0.00%) 0 0 / 312 (0.00%) 0 0	0 / 299 (0.00%) 0 0 / 299 (0.00%) 0 0 / 299 (0.00%) 0 0	

subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Bronchitis chronic subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Respiratory failure subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Bronchospasm subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Psychiatric disorders Restlessness subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Insomnia subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Agitation subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Investigations Weight decreased subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Injury, poisoning and procedural complications Traumatic brain injury subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Overdose subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Head injury subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Congenital, familial and genetic disorders			

Hip dysplasia subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Atrial septal defect subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Double ureter subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Hydrocele subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Hypospadias subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Strabismus congenital subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Nervous system disorders Febrile convulsion subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Ear and labyrinth disorders Otorrhoea subjects affected / exposed occurrences (all) Ear pain subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0 0 / 312 (0.00%) 0	0 / 299 (0.00%) 0 0 / 299 (0.00%) 0	
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all) Dacryostenosis acquired subjects affected / exposed occurrences (all) Conjunctivitis allergic	0 / 312 (0.00%) 0 0 / 312 (0.00%) 0	0 / 299 (0.00%) 0 0 / 299 (0.00%) 0	

subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Gastrointestinal disorders			
Coeliac disease			
subjects affected / exposed	0 / 312 (0.00%)	1 / 299 (0.33%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SE is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[19]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			

subjects affected / exposed	1 / 312 (0.32%)	0 / 299 (0.00%)	
occurrences (all)	1	0	
Dermatitis diaper			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Rash generalised			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[20]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[21]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[22]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[23]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[24]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Erythema (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[25]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[26]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[27]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[28]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[29]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[30]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[31]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[32]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Erythema (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[33]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Erythema (Mild) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[34]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Erythema (Moderate) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[35]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Tenderness (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[36]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Tenderness (Significant) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[37]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[38]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Mild) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[39]	0 / 312 (0.00%)	0 / 299 (0.00%)	
occurrences (all)	0	0	
Induration (Moderate) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed^[40] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Erythema (Any) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[41] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
Erythema (Mild) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[42] occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Erythema (Moderate) Infant Series Dose 3 alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed^[43] occurrences (all)	Additional description: Subjects affected and occurrences for LR is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
Renal and urinary disorders Pyelocaliectasis subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0	0 / 299 (0.00%) 0	
Musculoskeletal and connective tissue disorders Torticollis subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all)	0 / 312 (0.00%) 0 0 / 312 (0.00%) 0	0 / 299 (0.00%) 0 0 / 299 (0.00%) 0	
Infections and infestations Tuberculosis subjects affected / exposed occurrences (all) Bronchitis	0 / 312 (0.00%) 0	1 / 299 (0.33%) 1	

subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Bronchopneumonia		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Ear infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Nasopharyngitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Rhinitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Varicella		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Gastroenteritis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Upper respiratory tract infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Pharyngitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Respiratory tract infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Otitis media		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Laryngitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Otitis media acute		

subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Bronchiolitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Acute tonsillitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Pneumonia		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Tonsillitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Coxsackie viral infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Conjunctivitis bacterial		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Viral infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Dacryocystitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Urinary tract infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Gastroenteritis rotavirus		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Oral candidiasis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Candidiasis		

subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Viral skin infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Influenza		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Lower respiratory tract infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Acarodermatitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Cystitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Fungal infection		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Herpangina		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Impetigo		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Respiratory syncytial virus bronchiolitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Skin candida		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0
Tracheitis		
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (0.00%)
occurrences (all)	0	0

Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 312 (0.00%)	0 / 299 (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.

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[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.

for all days.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 May 2006	1. Changed measles, mumps, rubella vaccine (MMR) window to 365 to 395 days of age. 2. Added Hib as a component of Infanrix hexa.
15 November 2006	1. Added sentence stating that rotavirus vaccine may be given concomitantly with study vaccines.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported