



Clinical trial results:

A Phase 3, Randomized, Active-Controlled, Double-Blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of 3 Lots of 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given With Routine Pediatric Vaccinations in the United States

Summary

EudraCT number	2008-003688-38
Trial protocol	Outside EU/EEA
Global end of trial date	09 June 2008

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	06 August 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-3005
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00444457
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 800 7181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 800 7181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 November 2009
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	09 June 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immune responses induced by 3 lots of 13 valent pneumococcal conjugate vaccine (13vPnC) are equivalent when measured 1 month after the infant series.
To demonstrate that the immune responses induced by Pediarix given with 13vPnC are non-inferior to the immune responses induced by Pediarix given with 7 valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month after the infant series. Responses to the following antigens in Pediarix will be assessed: tetanus; poliovirus types 1, 2, and 3; and hepatitis B.
To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and adverse events (AEs).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 August 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1712
Worldwide total number of subjects	1712
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	1712
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1712 subjects from United States were enrolled in the study. The study started on 15 Aug 2007 and completed on 09 Jun 2008.

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 (Pilot Lot 1) Infant Series

Arm description:

Subjects received single dose of 13vPnC pilot lot 1 at 2, 4, and 6 months of age (infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available (Haemophilus influenzae type b) Hib vaccine at 2, 4, and 6 months of age.

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:

13vPnC was administered at a dose of 0.5 (milliliter) mL into the anterolateral thigh muscle of the left leg at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Pediarix was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Hib was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

Arm title	13vPnC (Pilot Lot 2) Infant Series
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Arm description:

Subjects received 1 single dose of 13vPnC pilot lot 2 at 2, 4, and 6 months of age (infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.

Arm type	Experimental
Investigational medicinal product name	13vPnC Pilot lot 2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

13vPnC was administered at a dose of 0.5 mL into the anterolateral thigh muscle of the left leg at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Pediarix was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Hib was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

Arm title	13vPnC (Manufacturing lot) Infant series
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Arm description:

Subjects received 1 single 0.5 mL dose of 13vPnC manufacturing lot (manu lot) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.

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

Dosage and administration details:

13vPnC was administered at a dose of 0.5 mL into the anterolateral thigh muscle of the left leg at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Pediarix was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Pediarix was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

Arm title	7vPnC Infant series
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Arm description:

Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.

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

Dosage and administration details:

7vPnC was administered at a dose of 0.5 mL into the anterolateral thigh muscle of the left leg at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Pediarix was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

Hib was administered at a dose of 0.5 mL on 2, 4, and 6 months of age (infant series).

Number of subjects in period 1	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series
Started	489	488	489
Vaccinated Dose 1	486	484	485
Vaccinated Dose 2	455	447	455
Vaccinated Dose 3	442	435	438
Completed	435	427	428
Not completed	54	61	61
Parent or legal guardian request	18	29	34
Failed to return	5	4	4
Adverse Event	1	2	2
Death	-	1	1
Unknown	-	1	-
Protocol Violation	16	8	6
Unspecified	-	2	4
Lost to follow-up	10	11	7

Investigator request	4	3	3
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Number of subjects in period 1	7vPnC Infant series
Started	246
Vaccinated Dose 1	244
Vaccinated Dose 2	228
Vaccinated Dose 3	225
Completed	218
Not completed	28
Parent or legal guardian request	14
Failed to return	2
Adverse Event	-
Death	1
Unknown	-
Protocol Violation	3
Unspecified	-
Lost to follow-up	6
Investigator request	2

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC (Pilot Lot 1) After Infant Series

Arm description:

Subjects received single dose of 13vPnC pilot lot 1 at 2, 4, and 6 months of age (in infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	13vPnC (Pilot Lot 2) After Infant Series

Arm description:

Subjects received single dose of 13vPnC pilot lot 2 at 2, 4, and 6 months of age (in infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.

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

Arm title	13vPnC (Manufacturing lot) After Infant series
Arm description:	
Subjects received single dose of 13vPnC manu lot at 2, 4, and 6 months of age (in infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	7vPnC After Infant series
Arm description:	
Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2^[1]	13vPnC (Pilot Lot 1) After Infant Series	13vPnC (Pilot Lot 2) After Infant Series	13vPnC (Manufacturing lot) After Infant series
Started	435	427	427
Completed	415	397	408
Not completed	20	30	19
Parent or legal guardian request	4	11	6
Failed to return	7	6	5
Adverse Event	2	2	-
Lost to Follow-up	-	-	-
Unknown	-	1	1
Protocol Violation	2	4	2
Unspecified	-	1	-
Lost to follow-up	5	5	5
Investigator request	-	-	-

Number of subjects in period 2^[1]	7vPnC After Infant series
Started	218
Completed	208
Not completed	10
Parent or legal guardian request	3
Failed to return	1
Adverse Event	-
Lost to Follow-up	2
Unknown	1
Protocol Violation	2
Unspecified	-

Lost to follow-up	-
Investigator request	1

Notes:

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

Justification: The subjects in this group received only the toddler dose.

Period 3

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC (Pilot Lot 1) Toddler Dose

Arm description:

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 1 at 12 months of age (toddler dose); a commercially available (Measles, Mumps, and Rubella-varicella vaccine) MMR-varicella, or if not available, a commercially available MMR at 12 months of age and a commercially available varicella vaccine administered in separate injections; and a commercially available (hepatitis A vaccine) HAV administered at 12 months of age.

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:

13vPnC was administered at a dose of 0.5 (milliliter) mL into the anterolateral thigh muscle of the left leg at 2, 4, and 6 months of age (infant series).

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

Dosage and administration details:

MMR-varicella was administered at a dose of 0.5mL on 12 months (toddler dose) of age.

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

Dosage and administration details:

HAV was administered at a dose of 0.5 mL on 12 months (toddler dose) of age.

Arm title	13vPnC (Pilot Lot 2) Toddler dose
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Arm description:

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 2 at 12 months of age (toddler dose); a

commercially available MMR-varicella administered at 12 months of age, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.

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:

113vPnC was administered at a dose of 0.5 mL into the anterolateral thigh muscle of the left leg at 12 months of age (toddler dose).

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

Dosage and administration details:

MMR-varicella was administered at a dose of 0.5mL on 12 months (toddler dose) of age.

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

Dosage and administration details:

HAV was administered at a dose of 0.5 mL on 12 months (toddler dose) of age.

Arm title	13vPnC (Manufacturing lot) Toddler dose
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Arm description:

Subjects received 1 single 0.5 mL dose of 13vPnC manu lot at 12 months of age (toddler dose); a commercially available MMR-varicella administered at 12 months of age, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.

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:

13vPnC was administered at a dose of 0.5 mL into the anterolateral thigh muscle of the left leg at 12 months of age (toddler dose).

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

Dosage and administration details:

MMR-varicella was administered at a dose of 0.5mL on 12 months (toddler dose) of age.

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

Dosage and administration details:

HAV was administered at a dose of 0.5 mL on 12 months (toddler dose) of age.

Arm title	7vPnC Toddler Dose
Arm description: Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 12 months of age (toddler dose); a commercially available MMR-varicella, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.	
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:

7vPnC was administered at a dose of 0.5 mL into the anterolateral thigh muscle of the left leg at 12 months of age (toddler dose).

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

Dosage and administration details:

MMR-varicella was administered at a dose of 0.5mL on 12 months (toddler dose) of age.

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

Dosage and administration details:

HAV was administered at a dose of 0.5 mL on 12 months (toddler dose) of age.

Number of subjects in period 3	13vPnC (Pilot Lot 1) Toddler Dose	13vPnC (Pilot Lot 2) Toddler dose	13vPnC (Manufacturing lot) Toddler dose
Started	415	397	408
Completed	408	391	404
Not completed	7	6	4
Parent or legal guardian request	-	3	2
Failed to return	2	2	1
Protocol Violation	1	-	-
Lost to follow-up	4	1	1

Number of subjects in period 3	7vPnC Toddler Dose
Started	208
Completed	200
Not completed	8
Parent or legal guardian request	1
Failed to return	3
Protocol Violation	1
Lost to follow-up	3

Baseline characteristics

Reporting groups

Reporting group title	13vPnC (Pilot Lot 1) Infant Series
Reporting group description: Subjects received single dose of 13vPnC pilot lot 1 at 2, 4, and 6 months of age (infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available (Haemophilus influenzae type b) Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Pilot Lot 2) Infant Series
Reporting group description: Subjects received 1 single dose of 13vPnC pilot lot 2 at 2, 4, and 6 months of age (infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Manufacturing lot) Infant series
Reporting group description: Subjects received 1 single 0.5 mL dose of 13vPnC manufacturing lot (manu lot) at 2, 4, and 6 months of age (infant series; co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	7vPnC Infant series
Reporting group description: Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	

Reporting group values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series
Number of subjects	489	488	489
Age categorical Units: Subjects			

Age continuous Units: months arithmetic mean standard deviation	2.2 ± 0.3	2.2 ± 0.3	2.2 ± 0.3
Gender categorical Units: Subjects			
Female	230	226	213
Male	259	260	275
Unknown	0	2	1

Reporting group values	7vPnC Infant series	Total	
Number of subjects	246	1712	
Age categorical Units: Subjects			

Age continuous			
Units: months			
arithmetic mean	2.2		
standard deviation	± 0.3	-	
Gender categorical			
Units: Subjects			
Female	115	784	
Male	131	925	
Unknown	0	3	

End points

End points reporting groups

Reporting group title	13vPnC (Pilot Lot 1) Infant Series
Reporting group description: Subjects received single dose of 13vPnC pilot lot 1 at 2, 4, and 6 months of age (infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available (Haemophilus influenzae type b) Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Pilot Lot 2) Infant Series
Reporting group description: Subjects received 1 single dose of 13vPnC pilot lot 2 at 2, 4, and 6 months of age (infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Manufacturing lot) Infant series
Reporting group description: Subjects received 1 single 0.5 mL dose of 13vPnC manufacturing lot (manu lot) at 2, 4, and 6 months of age (infant series; co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	7vPnC Infant series
Reporting group description: Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Pilot Lot 1) After Infant Series
Reporting group description: Subjects received single dose of 13vPnC pilot lot 1 at 2, 4, and 6 months of age (in infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Pilot Lot 2) After Infant Series
Reporting group description: Subjects received single dose of 13vPnC pilot lot 2 at 2, 4, and 6 months of age (in infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Manufacturing lot) After Infant series
Reporting group description: Subjects received single dose of 13vPnC manu lot at 2, 4, and 6 months of age (in infant series) co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	7vPnC After Infant series
Reporting group description: Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age.	
Reporting group title	13vPnC (Pilot Lot 1) Toddler Dose
Reporting group description: Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 1 at 12 months of age (toddler dose); a commercially available (Measles, Mumps, and Rubella-varicella vaccine) MMR-varicella, or if not available, a commercially available MMR at 12 months of age and a commercially available varicella vaccine administered in separate injections; and a commercially available (hepatitis A vaccine) HAV administered at 12 months of age.	

Reporting group title	13vPnC (Pilot Lot 2) Toddler dose
Reporting group description:	
Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 2 at 12 months of age (toddler dose); a commercially available MMR-varicella administered at 12 months of age, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.	
Reporting group title	13vPnC (Manufacturing lot) Toddler dose
Reporting group description:	
Subjects received 1 single 0.5 mL dose of 13vPnC manu lot at 12 months of age (toddler dose); a commercially available MMR-varicella administered at 12 months of age, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.	
Reporting group title	7vPnC Toddler Dose
Reporting group description:	
Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 12 months of age (toddler dose); a commercially available MMR-varicella, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.	
Subject analysis set title	Combined 13vPnC
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received 1 single 0.5 milliliter (mL) dose of 13-valent pneumococcal conjugate vaccine (13vPnC) pilot lot 1 or 2, or manufacturing lot at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose); co-administered with Pediarix® (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Haemophilus influenzae type b (Hib) vaccine at 2, 4, and 6 months of age; a commercially available Measles, Mumps, and Rubella-varicella vaccine (MMR-varicella), or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available hepatitis A vaccine (HAV) administered at 12 months of age.	
Subject analysis set title	13vPnC (Pilot lot 2) Toddler dose
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 2 at 12 months of age (toddler dose); a commercially available MMR-varicella administered at 12 months of age, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.	

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in the Three 13vPnC Groups 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in the Three 13vPnC Groups 1 Month After the Infant Series
End point description:	
Antibody geometric mean concentration (GMC) as measured by micrograms per milliliter (mcg/mL) for 7 common pneumococcal serotypes (serotypes (S) 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% confidence intervals (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Evaluable immunogenicity population: treatments as randomized at all expected doses, blood drawn within specified timeframes, at least 1 valid and determinate assay result for proposed analysis, and no major protocol violations. n=number of subjects with IgG antibody concentration to given serotype for the three 13vPnC lots, respectively.	
End point type	Primary
End point timeframe:	
1 Month after the infant series (7 Months of age)	

End point values	13vPnC (Pilot Lot 1) After Infant Series	13vPnC (Pilot Lot 2) After Infant Series	13vPnC (Manufacturing lot) After Infant series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	413	404	399	
Units: GMC microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=411, 404, 398)	1.33 (1.24 to 1.43)	1.34 (1.25 to 1.44)	1.75 (1.63 to 1.88)	
Common serotypes - serotype 6B (n=409, 401, 396)	2.89 (2.58 to 3.23)	2.15 (1.91 to 2.42)	2.54 (2.27 to 2.85)	
Common serotypes - serotype 9V (n=411, 403, 396)	1.05 (0.98 to 1.12)	1.11 (1.04 to 1.19)	1.11 (1.04 to 1.19)	
Common serotypes - serotype 14 (n=398, 387, 387)	4.97 (4.59 to 5.37)	5.13 (4.7 to 5.59)	5.18 (4.72 to 5.69)	
Common serotypes - serotype 18C (n=413, 401, 398)	1.3 (1.22 to 1.38)	1.34 (1.24 to 1.44)	1.48 (1.38 to 1.58)	
Common serotypes - serotype 19F (n=408, 399, 398)	1.85 (1.71 to 1.99)	2.07 (1.92 to 2.24)	2.59 (2.4 to 2.78)	
Common serotypes - serotype 23F (n=411, 402, 399)	1.24 (1.13 to 1.36)	1.27 (1.15 to 1.4)	1.03 (0.94 to 1.14)	
Additional serotypes - serotype 1 (n=411, 403, 395)	1.62 (1.5 to 1.76)	1.81 (1.66 to 1.98)	1.91 (1.76 to 2.07)	
Additional serotypes - serotype 3 (n=406, 391, 393)	0.52 (0.48 to 0.55)	0.56 (0.52 to 0.61)	0.61 (0.57 to 0.66)	
Additional serotypes - serotype 5 (n=412, 402, 393)	1.35 (1.24 to 1.47)	1.05 (0.96 to 1.14)	1.35 (1.25 to 1.47)	
Additional serotypes - serotype 6A (n=413, 402, 398)	2.4 (2.21 to 2.61)	2.1 (1.92 to 2.29)	2.12 (1.96 to 2.3)	
Additional serotypes - serotype 7F (n=412, 401, 397)	2.54 (2.37 to 2.71)	2.52 (2.35 to 2.7)	2.67 (2.5 to 2.85)	
Additional serotype - serotype 19A (n=411, 403, 397)	1.85 (1.71 to 2)	2 (1.85 to 2.16)	1.88 (1.74 to 2.02)	

Statistical analyses

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	difference in log-transformed GM
Point estimate	-0.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.09

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	-0.17

Statistical analysis title	S4:13vPnC (Pilot Lot 2) vs.13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	-0.16

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	0.46

Statistical analysis title

S6B:13vPnC (Pilot Lot 1) vs 13vPnC (Manu Lot)

Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.29

Statistical analysis title

S6B:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)

Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
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Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	-0.01

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.04

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.04

Statistical analysis title	S9v:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.1

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.09

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.08

Statistical analysis title	S14:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.11

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.07

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) After Infant series v 13vPnC (Pilot Lot 1) After Infant Series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	-0.03

Statistical analysis title	S18C:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series

Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	-0.01

Statistical analysis title	S19F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	-0.11

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.11

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) After Infant series v 13vPnC (Pilot Lot 1) After Infant Series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.31

Statistical analysis title	S23F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	0.34

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series

Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.01

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) After Infant series v 13vPnC (Pilot Lot 1) After Infant Series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	-0.04

Statistical analysis title	S1:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.06

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.02

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	-0.07

Statistical analysis title	S3:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.02

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	0.37

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.12

Statistical analysis title	S5:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	-0.13

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.25

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.24

Statistical analysis title	S6A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.11

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.1

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.04

Statistical analysis title	S7F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.04

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series

Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.03

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.09

Statistical analysis title	S19A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.17

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 3 lots were considered equivalent if the maximum difference between any 2 lots is less than 0.693 and greater than -0.693 using the equivalence testing procedure for 3 vaccine groups given by Wiens and Iglewicz, for all 13 serotypes. The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) After Infant series v 13vPnC (Pilot Lot 1) After Infant Series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.11

Primary: Percentage of Subjects Achieving Predefined Antibody Level ≥ 0.1 International Units Per Milliliter (IU/mL) for Tetanus Toxoid in the Combined 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level ≥ 0.1 International Units Per Milliliter (IU/mL) for Tetanus Toxoid in the Combined 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series
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End point description:

Percentage of subjects achieving predefined antibody threshold ≥ 0.1 IU/ mL along with the corresponding 95% CI for concomitant antigen tetanus toxoid are presented. Exact 2-sided CI was based on the observed proportion of subjects. Combined 13vPnC group includes subjects randomized to pilot lot 1, pilot lot 2, or the manu lot. Evaluable immunogenicity population. Combined 13vPnC group includes subjects who received pilot lot 1, pilot lot 2, or manu lot.

End point type	Primary
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End point timeframe:

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

End point values	7vPnC After Infant series	Combined 13vPnC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	196	184		
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)	98.5 (95.6 to 99.7)	98.4 (95.3 to 99.7)		

Statistical analyses

Statistical analysis title	Tetanus toxoid
Statistical analysis description:	
Difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage. For each of the 5 concomitant antigens (tetanus toxoid, poliovirus Type 1, 2, and 3, and hepatitis b antibodies), non-inferiority was shown if the lower limit of the 2-sided 95% CI, computed using the Chan and Zhang procedure for the difference in proportions, is greater than -10%.	
Comparison groups	7vPnC After Infant series v Combined 13vPnC
Number of subjects included in analysis	380
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	3

Primary: Percentage of Subjects Achieving Predefined Antibody Level $\geq 1:8$ for Poliovirus in the Combined 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level $\geq 1:8$ for Poliovirus in the Combined 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series
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End point description:

Percentage of subjects achieving predefined antibody threshold $\geq 1:8$ along with the corresponding 95% CI for concomitant antigen poliovirus type 1, type 2, and type 3 (Sabin strains 1, 2, 3) are presented. Exact 2-sided CI was based on the observed proportion of subjects. Combined 13vPnC group includes subjects randomized to pilot lot 1, pilot lot 2, or the manufacturing lot. Evaluable immunogenicity population; N=number of subjects analyzed with a determinate post-third dose IgG antibody concentration to the given concomitant vaccine component; n)=number of subjects with an antibody titer \geq prespecified level for given concomitant vaccine antigen for combined 13vPnC and 7vPnC, respectively.

End point type	Primary
End point timeframe:	
1 month after the infant series (7 months of age)	

End point values	7vPnC After Infant series	Combined 13vPnC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	187	183		
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)				
Poliovirus type 1 (n=183, 187)	100 (98 to 100)	100 (98 to 100)		
Poliovirus type 2 (n=181, 186)	99.5 (97.1 to 100)	98.9 (96.1 to 99.9)		
Poliovirus type 3 (n=182, 186)	99.5 (97.1 to 100)	98.9 (98 to 100)		

Statistical analyses

Statistical analysis title	Poliovirus type 1
Statistical analysis description:	
Difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage. For each of the 5 concomitant antigens (tetanus toxoid, poliovirus Type 1, 2, and 3, and hepatitis b antibodies), non-inferiority was shown if the lower limit of the 2-sided 95% CI, computed using the Chan and Zhang procedure for the difference in proportions, is greater than -10%. Exact 2-sided CI for difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage.	
Comparison groups	7vPnC After Infant series v Combined 13vPnC
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2

Statistical analysis title	Poliovirus type 2
Statistical analysis description:	
Difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage. For each of the 5 concomitant antigens (tetanus toxoid, poliovirus Type 1, 2, and 3, and hepatitis b antibodies), non-inferiority was shown if the lower limit of the 2-sided 95% CI, computed using the Chan and Zhang procedure for the difference in proportions, is greater than -10%. Exact 2-sided CI for difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage.	
Comparison groups	7vPnC After Infant series v Combined 13vPnC
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	2

Statistical analysis title	Poliovirus type 3
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Statistical analysis description:

Difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage. For each of the 5 concomitant antigens (tetanus toxoid, poliovirus Type 1, 2, and 3, and hepatitis b antibodies), non-inferiority was shown if the lower limit of the 2-sided 95% CI, computed using the Chan and Zhang procedure for the difference in proportions, is greater than -10%. Exact 2-sided CI for difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	7vPnC After Infant series v Combined 13vPnC
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	3

Primary: Percentage of Subjects Achieving Predefined Antibody Level ≥ 10.0 Milli-International Units Per Milliliter (mIU/mL) for Hepatitis B in the Combined 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Predefined Antibody Level ≥ 10.0 Milli-International Units Per Milliliter (mIU/mL) for Hepatitis B in the Combined 13vPnC Group Relative to 7vPnC Group 1 Month After the Infant Series
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End point description:

Percentage of subjects achieving predefined antibody threshold ≥ 10.0 mIU/ mL along with the corresponding 95% CI for concomitant antigen hepatitis B are presented. Exact 2-sided CI was based on the observed proportion of subjects. Combined 13vPnC group includes subjects randomized to pilot lot 1, pilot lot 2, or the manufacturing lot. Evaluable immunogenicity population; N=number of subjects analyzed with a determinate post-third dose IgG antibody concentration to the given concomitant vaccine component.

End point type	Primary
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End point timeframe:

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

End point values	7vPnC After Infant series	Combined 13vPnC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	173	153		
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)	100 (97.9 to 100)	100 (97.6 to 100)		

Statistical analyses

Statistical analysis title	Hepatitis B
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Statistical analysis description:

Difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage. For each of the 5 concomitant antigens (tetanus toxoid, poliovirus Type 1, 2, and 3, and hepatitis b antibodies), non-inferiority was shown if the lower limit of the 2-sided 95% CI, computed using the Chan and Zhang procedure for the difference in proportions, is greater than -10%. Exact 2-sided CI for difference in proportions (combined 13vPnC, 7vPnC) expressed as a percentage.

Comparison groups	7vPnC After Infant series v Combined 13vPnC
Number of subjects included in analysis	326
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	2.2

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 0.35 Mcg/mL in the Three 13vPnC Groups 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 0.35 Mcg/mL in the Three 13vPnC Groups 1 Month After the Infant Series
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End point description:

Percentage of subjects achieving predefined antibody threshold ≥ 0.35 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable immunogenicity population; (n)=number of subjects with a determinate IgG antibody concentration to the given serotype for the three 13vPnC lots, respectively.

End point type	Secondary
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End point timeframe:

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

End point values	13vPnC (Pilot Lot 1) After Infant Series	13vPnC (Pilot Lot 2) After Infant Series	13vPnC (Manufacturing lot) After Infant series	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	413	404	399	
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=411, 404, 398)	97.6 (95.6 to 98.8)	95.5 (93 to 97.3)	98.5 (96.7 to 99.4)	
Common serotypes - serotype 6B (n=409, 401, 396)	94.9 (92.3 to 96.8)	89.5 (86.1 to 92.3)	94.4 (91.7 to 96.5)	
Common serotypes - serotype 9V (n=411, 403, 396)	95.4 (92.9 to 97.2)	95.5 (93 to 97.3)	96.5 (94.1 to 98.1)	
Common serotypes - serotype 14 (n=398, 387, 387)	99.2 (97.8 to 99.8)	99 (97.4 to 99.7)	98.2 (96.3 to 99.3)	

Common serotypes - serotype 18C (n=413, 401, 398)	97.8 (95.9 to 99)	95.8 (93.3 to 97.5)	98.7 (96.1 to 99.1)
Common serotypes - serotype 19F (n=408, 399, 398)	97.8 (95.9 to 99)	97.5 (95.4 to 98.8)	98 (97.8 to 99.8)
Common serotypes - serotype 23F (n=411, 402, 399)	91.2 (88.1 to 93.8)	88.1 (84.5 to 91.1)	99.2 (83.5 to 90.3)
Additional serotypes - serotype 1 (n=411, 403,395)	97.8 (95.9 to 99)	97 (94.9 to 98.5)	87.2 (96.7 to 99.4)
Additional serotypes - serotype 3 (n=406, 391,393)	68.5 (63.7 to 73)	72.4 (67.7 to 76.8)	98.5 (74.8 to 83)
Additional serotypes - serotype 5 (n=412, 402,393)	94.2 (91.5 to 96.2)	90.3 (87 to 93)	79.1 (91.6 to 96.5)
Additional serotypes - serotype 6A (n=413,402,398)	98.1 (96.2 to 99.2)	95.5 (93 to 97.3)	94.4 (96.4 to 99.3)
Additional serotypes - serotype 7F (n=412,401,397)	99.8 (98.7 to 100)	99 (97.5 to 99.7)	98.2 (98.6 to 100)
Additional serotype - serotype 19A (n=411,403,397)	98.1 (96.2 to 99.2)	99 (97.5 to 99.7)	99.7 (97.1 to 99.6)

Statistical analyses

Statistical analysis title	S4: 13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Pilot Lot 1) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.09
upper limit	1.1

Statistical analysis title	S4:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description:	
Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.58
upper limit	-0.58

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.55
upper limit	9.19

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	3.66

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Mau Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.82
upper limit	-1.1

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.13
upper limit	2.83

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.97
upper limit	1.73

Statistical analysis title	S9V:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.81
upper limit	1.88

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.27
upper limit	1.95

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	3.01

Statistical analysis title	S14:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	2.76

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series

Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	4.74

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	1216
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	1.99

Statistical analysis title	S18C:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.89
upper limit	0.23

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.93
upper limit	2.6

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.46
upper limit	0.28

Statistical analysis title	S19F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.87
upper limit	0.02

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	7.46

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	8.39

Statistical analysis title	S23F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.75
upper limit	5.46

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.48
upper limit	3.18

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.78
upper limit	1.34

Statistical analysis title	S1:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.77
upper limit	0.67

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.27
upper limit	2.45

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.8
upper limit	-4.57

Statistical analysis title	S3:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.76
upper limit	-0.74

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series

Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	7.69

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.52
upper limit	3.09

Statistical analysis title	S5:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.92
upper limit	-0.36

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.12
upper limit	5.23

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.22
upper limit	1.86

Statistical analysis title	S6A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.39
upper limit	-0.27

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	1216
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	2.3

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and gamma=0.000001.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.12
upper limit	1.18

Statistical analysis title	S7F: 13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	0.52

Statistical analysis title	S19A: 13PnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Pilot Lot 2) After Infant Series
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.91
upper limit	0.8

Statistical analysis title	S19A: 13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.	
Comparison groups	13vPnC (Pilot Lot 1) After Infant Series v 13vPnC (Manufacturing lot) After Infant series

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.69
upper limit	1.19

Statistical analysis title	S19A: 13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

Exact, unconditional 2-sided 95% CI on the pairwise difference in proportions were computed using the noninferiority procedure of Chan and Zhang, using the standardized test statistics and $\gamma=0.000001$.

Comparison groups	13vPnC (Pilot Lot 2) After Infant Series v 13vPnC (Manufacturing lot) After Infant series
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	2.04

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 0.35 Mcg/mL in the Three 13vPnC Groups 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 0.35 Mcg/mL in the Three 13vPnC Groups 1 Month After the Toddler Dose
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End point description:

Percentage of Subjects achieving predefined antibody threshold ≥ 0.35 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Exact 2-sided CI based on the observed proportion of Subjects.Evaluable immunogenicity population; (n)=number of subjects with a determinate IgG antibody concentration to the given serotype for the three 13vPnC lots, respectively.

End point type	Secondary
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End point timeframe:

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

End point values	13vPnC (Pilot Lot 1) Toddler Dose	13vPnC (Pilot Lot 2) Toddler dose	13vPnC (Manufacturing lot) Toddler dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	368	344	358	
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=364, 342, 355)	99.2 (97.6 to 99.8)	99.1 (97.5 to 99.8)	100 (99 to 100)	
Common serotypes - serotype 6B (n=368,341,357)	100 (99 to 100)	100 (98.9 to 100)	100 (99 to 100)	
Common serotypes - serotype 9V (n=368,342,357)	99.7 (98.5 to 100)	99.7 (98.4 to 100)	99.2 (97.6 to 99.8)	
Common serotypes - serotype 14 (n=366,344,358)	100 (99 to 100)	99.7 (98.4 to 100)	100 (99 to 100)	
Common serotypes - serotype 18C (n=362,341,354)	98.9 (97.2 to 99.7)	98.5 (96.6 to 99.5)	99.4 (98 to 99.9)	
Common serotypes - serotype 19F (n=362,342,353)	98.3 (96.4 to 99.4)	98.8 (97 to 99.7)	99.4 (98 to 99.9)	
Common serotypes - serotype 23F (n=362,340,353)	99.4 (98 to 99.9)	99.1 (97.4 to 99.8)	98.3 (96.3 to 99.4)	
Additional serotypes - serotype 1 (n=367,344,357)	100 (99 to 100)	99.1 (97.5 to 99.8)	99.2 (97.6 to 99.8)	
Additional serotypes - serotype 3 (n=366,343,356)	83.6 (79.4 to 87.3)	80.8 (76.2 to 84.8)	88.5 (84.7 to 91.6)	
Additional serotypes - serotype 5 (n=368,343,357)	99.7 (98.5 to 100)	99.4 (97.9 to 99.9)	99.7 (98.4 to 100)	
Additional serotypes - serotype 6A (n=366,342,355)	100 (99 to 100)	100 (98.9 to 100)	99.7 (98.4 to 100)	
Additional serotypes - serotype 7F (n=366,343,358)	100 (99 to 100)	99.4 (97.9 to 99.9)	99.4 (98 to 99.9)	
Additional serotype - serotype 19A (n=362,341,353)	100 (99 to 100)	100 (98.9 to 100)	100 (99 to 100)	

Statistical analyses

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots. Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.61
upper limit	1.81

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.39
upper limit	0.23

Statistical analysis title	S4:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.54
upper limit	0.2

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.02
upper limit	1.11

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.13
upper limit	1.06

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.25
upper limit	1.37

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	2.18

Statistical analysis title	S9V:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	2.18

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	1.62

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	1.04

Statistical analysis title	S14:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.61
upper limit	0.76

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.52
upper limit	2.39

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.04

Statistical analysis title	S18C:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.87
upper limit	0.74

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.55
upper limit	1.5

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.06
upper limit	0.57

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.21
upper limit	2.05

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	3.16

Statistical analysis title	S23F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.05
upper limit	2.87

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	2.53

Statistical analysis title	S1:3vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.79
upper limit	1.66

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.85
upper limit	8.55

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.99
upper limit	0.21

Statistical analysis title	S3:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Manufacturing lot) Toddler dose

Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.14
upper limit	-2.37

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1.84

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.27
upper limit	1.3

Statistical analysis title	S5:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.84
upper limit	1.02

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	1.08

Statistical analysis title	S6A13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose

Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	1.56

Statistical analysis title	S6A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	1.56

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	2.09

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	2

Statistical analysis title	S7F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.59
upper limit	1.49

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	712
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	1.09

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.05
upper limit	1.04

Statistical analysis title	S19A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.09
upper limit	1.07

Statistical analysis title	S6B:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	1.04

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	2.44

Statistical analysis title	S19F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	702
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.44
upper limit	1

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 1.00 Mcg/mL in the Combined 13vPnC Group 1 Month After the Infant Series

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 1.00 Mcg/mL in the Combined 13vPnC Group 1 Month After the Infant Series
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End point description:

Percentage of subjects achieving predefined antibody threshold ≥ 1.00 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable immunogenicity population; (n)=number of subjects with a determinate IgG antibody concentration to the given serotype for the combined 13vPnC lot.

End point type	Secondary
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End point timeframe:

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

End point values	Combined 13vPnC			
Subject group type	Subject analysis set			
Number of subjects analysed	1216			
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=1213)	70.7 (78.4 to 82.9)			
Common serotypes - serotype 6B (n=1206)	78.9 (68.1 to 73.3)			
Common serotypes - serotype 9V (n=1210)	55.7 (76.4 to 81.1)			
Common serotypes - serotype 14 (n=1172)	95.2 (52.9 to 58.5)			
Common serotypes - serotype 18C (n=1212)	68.7 (93.8 to 96.4)			
Common serotypes - serotype 19F (n=1205)	85.4 (66 to 71.3)			
Common serotypes - serotype 23F (n=1212)	60.1 (83.3 to 87.3)			
Additional serotypes - serotype 1 (n=1209)	75.2 (57.2 to 62.8)			

Additional serotypes - serotype 3 (n=1190)	21.3 (72.7 to 77.6)			
Additional serotypes - serotype 5 (n=1207)	60.3 (19 to 23.8)			
Additional serotypes - serotype 6A (n=1213)	85.1 (57.5 to 63.1)			
Additional serotypes - serotype 7F (n=1210)	92.8 (82.9 to 87)			
Additional serotypes - serotype 19A (n=1211)	80.8 (91.2 to 94.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 1.00 Mcg/mL in the Three 13vPnC Groups 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving Serotype-specific Pneumococcal IgG Antibody Level ≥ 1.00 Mcg/mL in the Three 13vPnC Groups 1 Month After the Toddler Dose
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End point description:

Percentage of subjects achieving predefined antibody threshold ≥ 1.00 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable immunogenicity population; (n)=number of subjects with a determinate IgG antibody concentration to the given serotype for the three 13vPnC lots, respectively.

End point type	Secondary
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End point timeframe:

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

End point values	13vPnC (Pilot Lot 1) Toddler Dose	13vPnC (Pilot Lot 2) Toddler dose	13vPnC (Manufacturing lot) Toddler dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	415	397	408	
Units: observed percentage of subjects				
arithmetic mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=364,342,355)	86 (82 to 89.4)	87.4 (96.2 to 99.4)	92.7 (89.5 to 95.2)	
Common serotypes - serotype 6B (n=368,341,357)	99.5 (98.1 to 99.9)	99.1 (93.6 to 98)	99.7 (98.4 to 100)	
Common serotypes - serotype 9V (n=368,342,357)	80.7 (76.3 to 84.6)	84.5 (97.9 to 99.9)	85.4 (81.3 to 88.9)	
Common serotypes - serotype 14 (n=366,344,358)	98.6 (96.8 to 99.6)	98.8 (83.4 to 90.7)	98.3 (96.4 to 99.4)	
Common serotypes - serotype 18C (n=362,341,354)	79.6 (75 to 83.6)	85 (97.5 to 99.8)	89.5 (85.9 to 92.5)	
Common serotypes - serotype 19F (n=362,342,353)	94.5 (91.6 to 96.6)	95.3 (80.2 to 88.2)	97.7 (95.6 to 99)	

Common serotypes - serotype 23F (n=362,340,353)	91.7 (88.4 to 94.3)	91.2 (97 to 99.7)	89.8 (86.2 to 92.8)	
Additional serotypes - serotype 1 (n=367,344,357)	91.8 (88.5 to 94.4)	91 (80.8 to 88.7)	94.4 (91.5 to 96.5)	
Additional serotypes - serotype 3 (n=366,343,356)	32 (27.2 to 37)	30.3 (92.5 to 97.3)	36.8 (31.8 to 42)	
Additional serotypes - serotype 5 (n=368,343,357)	94 (91.1 to 96.2)	91 (87.6 to 94)	93.6 (90.5 to 95.9)	
Additional serotypes - serotype 6A (n=366,342,355)	99.2 (97.6 to 99.8)	98.2 (87.5 to 93.8)	99.2 (97.6 to 99.8)	
Additional serotypes - serotype 7F (n=366,343,358)	98.1 (96.1 to 99.2)	96.2 (25.5 to 35.5)	98.6 (96.8 to 99.5)	
Additional serotype - serotype 19A (n=362,341,353)	100 (99 to 100)	99.4 (87.4 to 93.8)	99.7 (98.4 to 100)	

Statistical analyses

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.52
upper limit	3.63

Statistical analysis title	S4: 13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-6.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.3
upper limit	-2.15

Statistical analysis title	S4: 13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.85
upper limit	0.79

Statistical analysis title	S6B: 13vPnC (Pilot Lot 2) vs. 13vPnC (Pilot Lot 1)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	2.07

Statistical analysis title	S6B: 13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a

percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	1.06

Statistical analysis title

S6B:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)

Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.27
upper limit	0.75

Statistical analysis title

S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)

Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.46
upper limit	1.82

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-4.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.24
upper limit	0.76

Statistical analysis title	S9V:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	4.41

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.14
upper limit	1.73

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	2.39

Statistical analysis title	S14:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.46
upper limit	2.59

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.17
upper limit	0.2

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.31
upper limit	-4.7

Statistical analysis title	S18C:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.55
upper limit	0.46

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.23
upper limit	2.52

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.35
upper limit	-0.4

Statistical analysis title	S19F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.44
upper limit	0.33

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.67
upper limit	4.8

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose

Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.38
upper limit	6.28

Statistical analysis title	S23F: 13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.06
upper limit	5.82

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.34
upper limit	5.08

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.39
upper limit	1.18

Statistical analysis title	S1:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.45
upper limit	0.46

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	8.55

Statistical analysis title	S3:113vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.79
upper limit	2.16

Statistical analysis title	S3:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.51
upper limit	0.54

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.84
upper limit	7.13

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.14
upper limit	4.11

Statistical analysis title	S5:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose

Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.72
upper limit	1.4

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	3.02

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.62
upper limit	1.71

Statistical analysis title	S6A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	0.92

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	4.67

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose

Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.67
upper limit	1.55

Statistical analysis title	S7F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.11
upper limit	-0.01

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.

Comparison groups	13vPnC (Pilot Lot 2) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	2.1

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	823
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.75
upper limit	1.58

Statistical analysis title	S19A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The equivalence test of Wiens and Iglewicz used to evaluate consistency among the three 13vPnC lots.Exact unconditional 2-sided 95% CI on the pairwise difference in proportions; expressed as a percentage.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 2) Toddler dose
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.86
upper limit	1.05

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in the Three 13vPnC Groups 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody in the Three 13vPnC Groups 1 Month After the Toddler Dose
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End point description:

Antibody geometric mean concentration (GMC) as measured by mcg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and

corresponding 2-sided 95% confidence intervals (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Evaluable immunogenicity population; (n)=number of subjects with a determinate IgG antibody concentration to the given serotype for the three 13vPnC lots, respectively.

End point type	Secondary
End point timeframe:	
1 month after the toddler dose (13 months of age)	

End point values	13vPnC (Pilot Lot 1) Toddler Dose	13vPnC (Manufacturing lot) Toddler dose	13vPnC (Pilot lot 2) Toddler dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	413	399	404	
Units: GMC mcg/mL				
arithmetic mean (confidence interval 95%)				
Common serotypes - serotype 4 (n=364,355,342)	2.29 (2.11 to 2.48)	3.06 (2.79 to 3.35)	2.25 (2.07 to 2.44)	
Common serotypes - serotype 6B (n=368,357,341)	11.14 (10.24 to 12.11)	9.92 (9.15 to 10.75)	9.33 (8.55 to 10.19)	
Common serotypes - serotype 9V (n=368,357,342)	1.91 (1.76 to 2.06)	1.99 (1.84 to 2.15)	1.95 (1.8 to 2.1)	
Common serotypes - serotype 14 (n=366,358,344)	6.61 (6.06 to 7.22)	6.91 (6.32 to 7.56)	7.05 (6.42 to 7.74)	
Common serotypes - serotype 18C (n=362,354,341)	1.95 (1.78 to 2.12)	2.48 (2.27 to 2.71)	2.2 (2.01 to 2.41)	
Common serotypes - serotype 19F (n=362,353,342)	4.51 (4.05 to 5.03)	6.51 (5.91 to 7.18)	4.67 (4.23 to 5.14)	
Common serotypes - serotype 23F (n=362,353,340)	3.35 (3.02 to 3.71)	3.1 (2.81 to 3.43)	3.46 (3.14 to 3.82)	
Additional serotypes - serotype 1 (n=367,357,344)	2.75 (2.53 to 2.99)	3.01 (2.75 to 3.3)	2.95 (2.68 to 3.24)	
Additional serotypes - serotype 3 (n=366,356,343)	0.75 (0.69 to 0.81)	0.8 (0.74 to 0.87)	0.71 (0.65 to 0.77)	
Additional serotypes - serotype 5 (n=368,357,343)	3.11 (2.87 to 3.37)	2.8 (2.6 to 3.02)	2.63 (2.42 to 2.87)	
Additional serotypes - serotype 6A (n=366,355,342)	7.52 (6.93 to 8.17)	6.83 (6.3 to 7.41)	6.97 (6.41 to 7.59)	
Additional serotypes - serotype 7F (n=366,358,343)	4.35 (4.01 to 4.72)	4.58 (4.21 to 4.98)	4.24 (3.86 to 4.66)	
Additional serotype - serotype 19A (n=362,353,341)	8.41 (7.73 to 9.14)	8.6 (7.91 to 9.36)	8.32 (7.66 to 9.04)	

Statistical analyses

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description:	
The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose

Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.13

Statistical analysis title	S4:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	-0.17

Statistical analysis title	S4:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.06

Statistical analysis title	S6B:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	-0.19

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.3

Statistical analysis title	S6B:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.12

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.23

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.09

Statistical analysis title	S9V:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.07

Statistical analysis title	S9V:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
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Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.09

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.08

Statistical analysis title	S14:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.15

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0

Statistical analysis title	S18C:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.01

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.11

Statistical analysis title	S19F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	-0.22

Statistical analysis title	S19F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	-0.2

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
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Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.11

Statistical analysis title	S23F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.22

Statistical analysis title	S23F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.25

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.06

Statistical analysis title	S1:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.21
upper limit	0.03

Statistical analysis title	S1:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.11

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	0.18

Statistical analysis title	S3:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.04

Statistical analysis title	S3:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
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Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	-0.01

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	0.28

Statistical analysis title	S5:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.21

Statistical analysis title	S5:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.05

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.19

Statistical analysis title	S6A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.02
upper limit	0.21

Statistical analysis title	S6A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.14

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.15

Statistical analysis title	S7F:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
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Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.07

Statistical analysis title	S7F:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.05

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.13

Statistical analysis title	S19A:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Manufacturing lot) Toddler dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.1

Statistical analysis title	S19A:13vPnC (Pilot Lot 2) vs. 13vPnC (Manu Lot)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.08

Statistical analysis title	S14:13vPnC (Pilot Lot 1) vs. 13vPnC (Pilot Lot 2)
Statistical analysis description: The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.	
Comparison groups	13vPnC (Pilot Lot 1) Toddler Dose v 13vPnC (Pilot lot 2) Toddler dose
Number of subjects included in analysis	817
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.06

Statistical analysis title	S18C:13vPnC (Pilot Lot 1) vs. 13vPnC (Manu Lot)
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Statistical analysis description:

The 2-sided 95% CI were constructed for the mean difference of the logarithmically transformed geometric mean IgG antibody concentration between the two lots.

Comparison groups	13vPnC (Manufacturing lot) Toddler dose v 13vPnC (Pilot Lot 1) Toddler Dose
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Difference in log-transformed GM
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	-0.12

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

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

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

End point type	Other pre-specified
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End point timeframe:

Within 7 days after dose 1 (2 months of age)

End point values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series	7vPnC Infant series
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	425	416	407	214
Units: percentage of subjects				

number (not applicable)				
Tenderness: Any (n=420, 409, 400, 212)	62.4	64.1	62.5	67
Tenderness: Significant (n=348, 337, 345, 170)	9.2	10.4	10.4	12.9
Induration: Any (n=356, 347, 352, 176)	16.6	19.6	19.3	18.2
Induration: Mild (n=353, 344, 348, 173)	14.7	16.9	15.5	16.2
Induration: Moderate (n=338, 328, 340, 167)	3.6	5.8	5	3.6
Induration: Severe (n=333, 325, 335, 164)	0	0	0	0
Erythema: Any (n=355, 352, 360, 180)	19.4	25	23.1	22.8
Erythema: Mild (n=354, 352, 358, 180)	18.1	24.7	21.2	21.7
Erythema: Moderate (n=334, 326, 337, 164)	2.1	0.6	2.4	1.2
Erythema: Severe (n=333, 325, 335, 164)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

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

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

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

End point type	Other pre-specified
End point timeframe:	
Within 7 days after dose 2 (4 months of age)	

End point values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series	7vPnC Infant series
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	361	345	349	180
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=354, 330, 337, 176)	66.4	67.3	65	64.8
Tenderness: Significant (n=269, 231, 262, 132)	9.7	7.4	12.2	11.4
Induration: Any (n=291, 248, 279, 141)	24.4	22.6	28.7	17.7

Induration: Mild (n=288, 246, 276, 141)	22.6	22	26.8	17.7
Induration: Moderate (n=270, 224, 255, 128)	4.1	1.3	4.7	3.9
Induration: Severe (n=263, 221, 250, 127)	0	0	0.4	0
Erythema: Any (n=292, 265, 281, 153)	30.1	35.8	34.5	30.1
Erythema: Mild (n=289, 263, 279, 153)	28.4	34.6	33.3	28.8
Erythema: Moderate (n=268, 223, 252, 128)	3.4	1.8	3.2	3.1
Erythema: Severe (n=263, 221, 249, 127)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

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

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

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

End point type	Other pre-specified
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End point timeframe:

Within 7 days after dose 3 (6 months of age)

End point values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series	7vPnC Infant series
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	333	321	320	165
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=317, 304, 300, 156)	62.5	60.9	55	64.7
Tenderness: Significant (n=248, 226, 237, 118)	8.9	7.5	10.1	11.9
Induration: Any (n=263, 250, 262, 128)	27	23.6	28.6	30.5
Induration: Mild (n=260, 249, 260, 127)	24.6	22.5	27.3	29.1
Induration: Moderate (n=242, 221, 229, 114)	4.1	4.1	3.9	7
Induration: Severe (n=237, 217, 227, 111)	0	0	0	0
Erythema: Any (n=278, 262, 274, 137)	39.6	35.9	37.6	39.4

Erythema: Mild (n=275, 260, 272, 135)	37.1	33.8	36.4	38.5
Erythema: Moderate (n=243, 219, 231, 116)	5.3	4.1	5.6	7.8
Erythema: Severe (n=237, 217, 227, 111)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects Reporting Local Reactions in the Combined 13vPnC Group and 7vPnC Group: Toddler Dose (12 Months of Age)
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End point description:

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

End point type	Other pre-specified
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End point timeframe:

Within 7 days after dose (12 months of age)

End point values	7vPnC Toddler Dose	Combined 13vPnC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	106	889		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n= 131,826)	63.4	57.3		
Tenderness: Significant (n= 97, 630)	4.1	6.7		
Induration: Any (n=110,698)	43.6	31.5		
Induration: Mild (n=107, 689)	41.1	28.9		
Induration: Moderate (n= 101,627)	17.8	8.5		
Induration: Severe (n= 93,603)	0	0		
Erythema: Any (n=121,749)	52.9	42.6		
Erythema: Mild (n=116,735)	50	39.2		
Erythema: Moderate (n=104,631)	21.2	10.6		
Erythema: Severe (n=93,603)	0	0		

Statistical analyses

No statistical analyses for this end point

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

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

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

End point type	Other pre-specified
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End point timeframe:

Within 7 days after dose 1 (2 months of age)

End point values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series	7vPnC Infant series
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	465	457	456	237
Units: percentage of subjects				
number (not applicable)				
Fever ≥ 38 but ≤ 39 degrees C (n=353, 337, 353, 173)	24.6	23.4	24.6	26
Fever > 39 but ≤ 40 degrees C (n=328, 319, 333, 161)	0.6	0.3	0.9	1.2
Fever > 40 degrees C (n=328, 319, 331, 160)	0	0	0.3	0.6
Decreased appetite (n=393, 385, 386, 200)	50.6	46	50	49
Irritability (n=435, 432, 433, 226)	85.7	84.3	89.1	87.6
Increased sleep (n=425, 417, 402, 212)	71.5	72.7	69.4	72.6
Decreased sleep (n=379, 377, 377, 194)	44.1	46.9	42.2	46.4
Hives [urticaria] (n=333, 328, 335, 164)	0.6	0.9	0.6	0

Statistical analyses

No statistical analyses for this end point

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

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

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

End point type	Other pre-specified
End point timeframe:	
Within 7 days after dose 2 (4 months of age)	

End point values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series	7vPnC Infant series
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	400	398	410	208
Units: percentage of subjects				
number (not applicable)				
Fever ≥ 38 but ≤ 39 degrees C (n=290, 250, 290, 143)	33.4	36.4	35.5	28
Fever > 39 but ≤ 40 degrees C (n=263, 216, 248, 124)	3.4	3.2	3.6	0
Fever > 40 degrees C (n=259, 214, 245, 124)	0.4	0	0	0
Decreased appetite (n=322, 293, 325, 164)	48.4	49.1	48	49.4
Irritability (n=377, 370, 376, 201)	86.5	86.5	84.6	81.1
Increased sleep (n=332, 318, 343, 177)	64.8	68.2	67.3	63.3
Decreased sleep (n=324, 291, 305, 159)	49.1	48.8	44.6	48.4
Hives [urticaria] (n=263, 225, 253, 127)	0.4	2.2	1.6	0.8

Statistical analyses

No statistical analyses for this end point

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

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

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

End point type	Other pre-specified
End point timeframe:	
Within 7 days after dose 3 (6 months of age)	

End point values	13vPnC (Pilot Lot 1) Infant Series	13vPnC (Pilot Lot 2) Infant Series	13vPnC (Manufacturing lot) Infant series	7vPnC Infant series
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	373	365	373	192
Units: percentage of subjects				
number (not applicable)				
Fever ≥ 38 but ≤ 39 degrees C (n=266, 246, 252, 132)	26.3	27.6	31.7	32.6
Fever > 39 but ≤ 40 degrees C (n=237, 219, 231, 113)	2.5	3.7	5.6	6.2
Fever > 40 degrees C (n=234, 216, 224, 111)	0	0.5	0	0.9
Decreased appetite (n=286, 273, 286, 144)	45.8	48	50.7	50
Irritability (n=352, 339, 347, 186)	79.5	80.5	82.7	84.4
Increased sleep (n=289, 289, 286, 138)	55.4	58.8	59.8	51.4
Decreased sleep (n=282, 272, 289, 147)	42.6	50.4	48.4	56.5
Hives [urticaria] (n=239, 218, 229, 112)	1.7	0.9	1.7	1.8

Statistical analyses

No statistical analyses for this end point

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

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

Systemic events (any fever ≥ 38 degrees C, decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]) were reported using an electronic diary. subjects may be represented in more than 1 category. ~Safety population: all subjects who received at least 1 dose of study vaccine. N=number of subjects reporting any systemic events; (n)=number of subjects reporting yes for at least 1 day or no for all days for the combined 13vPnC group and 7vPnC, respectively.

End point type	Other pre-specified
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End point timeframe:

Within 7 days after dose (12 months of age)

End point values	7vPnC Toddler Dose	Combined 13vPnC		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	171	1001		
Units: percentage of subjects				
number (not applicable)				
Fever ≥ 38 but ≤ 39 degrees C (n=667, 107)	29.9	28.8		
Fever > 39 but ≤ 40 degrees C (n=592, 95)	5.3	4.4		

Fever >40 degrees C (n=586, 93)	0	1		
Decreased appetite (n=790, 115)	50.4	51.9		
Irritability (n=943, 160)	80	81.8		
Increased sleep (n=779, 126)	47.6	47.8		
Decreased sleep (n=770, 117)	42.7	46.9		
Hives [urticaria] (n=607, 96)	5.2	2.1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline through 6 Month Follow-up after last study vaccination (18 Months). Local reactions and systemic events assessed within 7 days of dose: Infant Series Dose 1, 2, and 3 at 2, 4, and 6 months of age, respectively; Toddler Dose at 12 months of age.

Adverse event reporting additional description:

Safety population = all randomized subjects with at least 1 dose of study treatment. An Adverse Event (AE) term may be reported as both a serious and non-serious AE, but are distinct events. AE may = serious for 1 subject and = non-serious for another subject or subject may have experienced both a serious and non-serious episode of the same event.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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Reporting groups

Reporting group title	Infant Series 13vPnC (Pilot Lot 1)
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 1 at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age (infant series). Other Adverse Events (non-serious events): the number affected (N) for non-systematic (unsolicited) Other Adverse Events N=407; systematic (solicited) Local Reactions N=262; systematic (solicited) Systemic Events N=373.

Reporting group title	Infant Series 13vPnC (Pilot Lot 2)
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 2 at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age (infant series). Other Adverse Events (non-serious events): the number affected (N) for non-systematic (unsolicited) Other Adverse Events N=394; systematic (solicited) Local Reactions N=262; systematic (solicited) Systemic Events N=364.

Reporting group title	Infant Series 13vPnC (Manu lot)
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC manu lot at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age (infant series). Other Adverse Events (non-serious events): the number affected (N) for non-systematic (unsolicited) Other Adverse Events N=402; systematic (solicited) Local Reactions N=250; systematic (solicited) Systemic Events N=386.

Reporting group title	Infant Series 7vPnC
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age (infant series). Other Adverse Events (non-serious events): the number affected (N) for non-systematic (unsolicited) Other Adverse Events N=207; systematic (solicited) Local Reactions N=142; systematic (solicited) Systemic Events N=198.

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

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 1, 2, or manu lot at 2, 4, and 6 months of age (assessment at 7 months of age; 1 month after the infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age (assessment at 7 months of age; 1 month after the infant series).

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

Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 2, 4, and 6 months of age (assessment at 7 months of age; 1 month after the infant series); co-administered with Pediarix (a commercially available combination diphtheria and tetanus toxoid; acellular pertussis and hepatitis B antigens; and inactivated poliovirus); and a commercially available Hib vaccine at 2, 4, and 6 months of age (assessment at 7 months of age; 1 month after the infant series).

Reporting group title	Toddler Dose Combined 13vPnC
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 1, 2, or manu lot at 12 months of age; co-administered with a commercially available MMR-varicella, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age.

Other Adverse Events (non-serious events): the number affected (N) for non-systematic (unsolicited) Other Adverse Events N=434; systematic (solicited) Local Reactions N=473; systematic (solicited) Systemic Events N=771.

Reporting group title	Toddler Dose 7vPnC
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 12 months of age; co-administered with a commercially available MMR-varicella, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age. Other Adverse Events (non-serious events): the number affected (N) for non-systematic (unsolicited) Other Adverse Events N=75; systematic (solicited) Local Reactions N=83; systematic (solicited) Systemic Events N=128.

Reporting group title	Post Toddler Dose 6-Month Follow-up Combined 13vPnC
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Reporting group description:

Subjects received 1 single 0.5 mL dose of 13vPnC pilot lot 1, 2, or manu lot at 12 months of age (assessment at 18 months of age; 6 months after the toddler dose); co-administered with a commercially available MMR-varicella, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age (assessment at 18 months of age; 6 months after the toddler dose).

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

Subjects received 1 single 0.5 mL dose of 7-valent pneumococcal conjugate vaccine (7vPnC) at 12 months of age (assessment at 18 months of age; 6 months after the toddler dose); co-administered with a commercially available MMR-varicella, or if not available, a commercially available MMR and a commercially available varicella vaccine administered in separate injections; and a commercially available HAV administered at 12 months of age (assessment at 18 months of age; 6 months after the toddler dose).

Serious adverse events	Infant Series 13vPnC (Pilot Lot 1)	Infant Series 13vPnC (Pilot Lot 2)	Infant Series 13vPnC (Manu lot)
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 486 (2.67%)	23 / 483 (4.76%)	17 / 483 (3.52%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Near drowning			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Skull fracture			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Accidental overdose			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Foreign body trauma			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary valve stenosis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
General disorders and administration			

site conditions			
Pyrexia			
subjects affected / exposed	0 / 486 (0.00%)	3 / 483 (0.62%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritability			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Injection site rash			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Immune system disorders			
Allergy to vaccine			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
Eye disorders			
Dacryostenosis acquired			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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			
Haematochezia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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			
Respiratory distress			
subjects affected / exposed	1 / 486 (0.21%)	3 / 483 (0.62%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apparent life threatening event			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Productive cough			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
Aspiration			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 aspiration			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Pulmonary oedema			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 arrest			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Asthma			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Bronchiolitis			
subjects affected / exposed	5 / 486 (1.03%)	2 / 483 (0.41%)	4 / 483 (0.83%)
occurrences causally related to treatment / all	1 / 5	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 486 (0.41%)	5 / 483 (1.04%)	4 / 483 (0.83%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	2 / 483 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 486 (0.00%)	3 / 483 (0.62%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	2 / 483 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 486 (0.00%)	3 / 483 (0.62%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess oral			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
Influenza			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
Meningitis aseptic			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis enteroviral			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 viral			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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
Urosepsis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (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 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (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
Cellulitis			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Eczema herpeticum			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Impetigo			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Osteomyelitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Perirectal abscess			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Skin infection			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Staphylococcal infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 upper respiratory tract infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Cellulitis pharyngeal			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Rectal abscess			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 rash			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Endocarditis bacterial			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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 / 486 (0.00%)	1 / 483 (0.21%)	3 / 483 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal loss of weight			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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
Failure to thrive			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (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	Infant Series 7vPnC	After the Infant Series Combined 13vPnC	After the Infant Series 7vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 244 (6.15%)	25 / 1445 (1.73%)	3 / 244 (1.23%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Thermal burn			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	1 / 244 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Near drowning			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Skull fracture			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Accidental overdose			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Foreign body trauma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Pulmonary valve stenosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
General disorders and administration			

site conditions			
Pyrexia			
subjects affected / exposed	2 / 244 (0.82%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Irritability			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (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
Injection site rash			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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 / 244 (0.00%)	1 / 1445 (0.07%)	1 / 244 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to vaccine			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Food allergy			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Dacryostenosis acquired			

subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Gastrointestinal disorders			
Haematochezia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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	1 / 244 (0.41%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory distress			
subjects affected / exposed	1 / 244 (0.41%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apparent life threatening event			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Hypoxia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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

Productive cough			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Stridor			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Aspiration			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Pulmonary oedema			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Asthma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Bronchiolitis			
subjects affected / exposed	2 / 244 (0.82%)	2 / 1445 (0.14%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 244 (0.82%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 244 (0.82%)	1 / 1445 (0.07%)	1 / 244 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (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	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (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
Gastroenteritis			
subjects affected / exposed	1 / 244 (0.41%)	2 / 1445 (0.14%)	0 / 244 (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
Otitis media			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Abscess oral			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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 aseptic			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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 enteroviral			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (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 viral			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Urosepsis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 244 (0.00%)	3 / 1445 (0.21%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema herpeticum			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Impetigo			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Osteomyelitis			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Perirectal abscess			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Pyelonephritis			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Skin infection			

subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Staphylococcal infection			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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 upper respiratory tract infection			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis pharyngeal			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Rectal abscess			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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 rash			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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
Endocarditis bacterial			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (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	2 / 244 (0.82%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal loss of weight			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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
Failure to thrive			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (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	Toddler Dose Combined 13vPnC	Toddler Dose 7vPnC	Post Toddler Dose 6- Month Follow-up Combined 13vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 1210 (0.74%)	1 / 208 (0.48%)	21 / 1443 (1.46%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Near drowning			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body trauma			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Pulmonary valve stenosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 / 1210 (0.08%)	0 / 208 (0.00%)	2 / 1443 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Pyrexia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Irritability			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Injection site rash			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Immune system disorders			
Allergy to vaccine			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Food allergy			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Dacryostenosis acquired			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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			
Haematochezia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
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			
Respiratory distress			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Apparent life threatening event			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Bronchial hyperreactivity			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (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
Hypoxia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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

Productive cough			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Stridor			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Aspiration			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 aspiration			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Pulmonary oedema			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 arrest			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Asthma			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	4 / 1443 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Bronchiolitis			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	3 / 1443 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	2 / 1443 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (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
Croup infectious			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	2 / 1443 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
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 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess oral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 aseptic			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 enteroviral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 viral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Urosepsis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Cellulitis			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	2 / 1443 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema herpeticum			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Impetigo			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Osteomyelitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (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
Skin infection			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Staphylococcal infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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 upper respiratory tract infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Cellulitis pharyngeal			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (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
Rectal abscess			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (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
Endocarditis bacterial			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (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
Abnormal loss of weight			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (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
Failure to thrive			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Post Toddler Dose 6-Month Follow-up 7vPnC		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 244 (2.87%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Near drowning			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body trauma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary valve stenosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration			

site conditions			
Pyrexia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden infant death syndrome			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Irritability			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injection site rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Allergy to vaccine			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food allergy			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Dacryostenosis acquired			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Haematochezia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Respiratory distress			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apparent life threatening event			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Productive cough			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stridor			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory arrest			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	2 / 244 (0.82%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			

Bronchiolitis				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 244 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Croup infectious				
subjects affected / exposed	1 / 244 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 244 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Otitis media				
subjects affected / exposed	2 / 244 (0.82%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				

subjects affected / exposed	1 / 244 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess oral				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis aseptic				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis enteroviral				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eczema herpeticum				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpangina				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impetigo				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital cellulitis				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perirectal abscess				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 244 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				

subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcal bacteraemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis pharyngeal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis bacterial			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abnormal loss of weight			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Infant Series 13vPnC (Pilot Lot 1)	Infant Series 13vPnC (Pilot Lot 2)	Infant Series 13vPnC (Manu lot)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	434 / 486 (89.30%)	428 / 483 (88.61%)	451 / 483 (93.37%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	1 / 486 (0.21%)	4 / 483 (0.83%)	0 / 483 (0.00%)
occurrences (all)	1	4	0
Haemangioma of skin			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	2	2	0
Melanocytic naevus			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Benign neoplasm			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Benign penile neoplasm			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Fibrous histiocytoma			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Neonatal disorder			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Umbilical granuloma			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	43 / 486 (8.85%)	49 / 483 (10.14%)	40 / 483 (8.28%)
occurrences (all)	53	51	46
Irritability			
subjects affected / exposed	15 / 486 (3.09%)	12 / 483 (2.48%)	7 / 483 (1.45%)
occurrences (all)	15	12	8
Injection site erythema			

subjects affected / exposed	1 / 486 (0.21%)	4 / 483 (0.83%)	1 / 483 (0.21%)
occurrences (all)	1	4	1
Injection site swelling			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	2	1	1
Injection site induration			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	2	0	1
Injection site pain			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	1	1	1
Xerosis			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	2	0	1
Injection site reaction			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Cyst			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Injection site dryness			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Injection site haemorrhage			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Injection site rash			

subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Injection site haematoma subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Injection site urticaria subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Developmental delay subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Localised oedema subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Fever ≥38°C but ≤39°C Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[1] occurrences (all)	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.		
	87 / 353 (24.65%) 87	79 / 337 (23.44%) 79	87 / 353 (24.65%) 87
Fever >39°C but ≤40°C Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	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.		
	2 / 328 (0.61%) 2	1 / 319 (0.31%) 1	3 / 333 (0.90%) 3
Fever >40°C Dose Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	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.		
	0 / 328 (0.00%) 0	0 / 319 (0.00%) 0	1 / 331 (0.30%) 1
Decreased appetite Infant Series Dose 1 and Toddler Dose alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic	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.		

subjects affected / exposed ^[4]	199 / 393 (50.64%)	177 / 385 (45.97%)	193 / 386 (50.00%)
occurrences (all)	199	177	193
Irritability 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	373 / 435 (85.75%)	364 / 432 (84.26%)	386 / 433 (89.15%)
occurrences (all)	373	364	386
Increased sleep 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	304 / 425 (71.53%)	303 / 417 (72.66%)	279 / 402 (69.40%)
occurrences (all)	304	303	279
Decreased sleep Infant 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[7]	167 / 379 (44.06%)	177 / 377 (46.95%)	159 / 377 (42.18%)
occurrences (all)	167	177	159
Hives (urticaria) Infant 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[8]	2 / 333 (0.60%)	3 / 328 (0.91%)	2 / 335 (0.60%)
occurrences (all)	2	3	2
Fever >39°C but ≤40°C Infant Series Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[9]	9 / 263 (3.42%)	7 / 216 (3.24%)	9 / 248 (3.63%)
occurrences (all)	9	7	9
Fever >40°C Dose Infant Series Dose 2	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 Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[10]	1 / 259 (0.39%)	0 / 214 (0.00%)	0 / 245 (0.00%)
occurrences (all)	1	0	0
Decreased appetite Infant Series Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[11]	156 / 322 (48.45%)	144 / 293 (49.15%)	156 / 325 (48.00%)
occurrences (all)	156	144	156
Irritability Infant Series Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[12]	326 / 377 (86.47%)	320 / 370 (86.49%)	318 / 376 (84.57%)
occurrences (all)	326	320	318
Increased sleep Infant Series Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[13]	215 / 332 (64.76%)	217 / 318 (68.24%)	231 / 343 (67.35%)
occurrences (all)	215	217	231
Decreased sleep Infant Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[14]	159 / 324 (49.07%)	142 / 291 (48.80%)	136 / 305 (44.59%)
occurrences (all)	159	142	136
Hives (urticaria) Infant Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[15]	1 / 263 (0.38%)	5 / 225 (2.22%)	4 / 253 (1.58%)
occurrences (all)	1	5	4
Fever ≥38°C but ≤39°C Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[16]	70 / 266 (26.32%)	68 / 246 (27.64%)	80 / 252 (31.75%)
occurrences (all)	70	68	80
Fever >39°C but ≤40°C Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[17]	6 / 237 (2.53%)	8 / 219 (3.65%)	13 / 231 (5.63%)
occurrences (all)	6	8	13
Fever >40°C Dose Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[18]	0 / 243 (0.00%)	1 / 216 (0.46%)	0 / 224 (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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[19]	131 / 286 (45.80%)	131 / 273 (47.99%)	145 / 286 (50.70%)
occurrences (all)	131	131	145
Irritability Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[20]	280 / 352 (79.55%)	273 / 339 (80.53%)	287 / 347 (82.71%)
occurrences (all)	280	273	287
Increased sleep Infant Series 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[21]	160 / 289 (55.36%)	170 / 289 (58.82%)	171 / 286 (59.79%)
occurrences (all)	160	170	171
Decreased sleep Infant Dose 3	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 Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[22]	120 / 282 (42.55%)	137 / 272 (50.37%)	140 / 289 (48.44%)
occurrences (all)	120	137	140
Hives (urticaria) Infant Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[23]	4 / 239 (1.67%)	2 / 218 (0.92%)	4 / 229 (1.75%)
occurrences (all)	4	2	4
Fever ≥38°C but ≤39°C Infant Series Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[24]	97 / 290 (33.45%)	91 / 250 (36.40%)	103 / 290 (35.52%)
occurrences (all)	97	91	103
Immune system disorders			
Milk allergy			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	4 / 483 (0.83%)
occurrences (all)	2	2	4
Drug hypersensitivity			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Food allergy			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Hypersensitivity			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Anaphylactic reaction			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Overfeeding of infant			

subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Reproductive system and breast disorders			
Vulval disorder			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	2	2	2
Penile adhesion			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	4 / 483 (0.83%)
occurrences (all)	1	0	4
Balanitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Breast cyst			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Genital discomfort			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Gynaecomastia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Genital labial adhesions			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Genital rash			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	59 / 486 (12.14%)	52 / 483 (10.77%)	51 / 483 (10.56%)
occurrences (all)	65	58	61
Nasal congestion			

subjects affected / exposed	43 / 486 (8.85%)	48 / 483 (9.94%)	34 / 483 (7.04%)
occurrences (all)	45	45	36
Rhinorrhoea			
subjects affected / exposed	21 / 486 (4.32%)	25 / 483 (5.18%)	18 / 483 (3.73%)
occurrences (all)	22	29	21
Wheezing			
subjects affected / exposed	18 / 486 (3.70%)	10 / 483 (2.07%)	15 / 483 (3.11%)
occurrences (all)	22	10	17
Bronchial hyperreactivity			
subjects affected / exposed	11 / 486 (2.26%)	11 / 483 (2.28%)	8 / 483 (1.66%)
occurrences (all)	11	13	8
Sneezing			
subjects affected / exposed	3 / 486 (0.62%)	3 / 483 (0.62%)	2 / 483 (0.41%)
occurrences (all)	3	4	2
Asthma			
subjects affected / exposed	1 / 486 (0.21%)	3 / 483 (0.62%)	4 / 483 (0.83%)
occurrences (all)	1	4	4
Rhinitis allergic			
subjects affected / exposed	4 / 486 (0.82%)	1 / 483 (0.21%)	2 / 483 (0.41%)
occurrences (all)	4	1	2
Sinus congestion			
subjects affected / exposed	1 / 486 (0.21%)	2 / 483 (0.41%)	3 / 483 (0.62%)
occurrences (all)	1	2	3
Pulmonary congestion			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	3	2	2
Bronchospasm			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	3
Dysphonia			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Upper respiratory tract congestion			
subjects affected / exposed	0 / 486 (0.00%)	3 / 483 (0.62%)	0 / 483 (0.00%)
occurrences (all)	0	4	0
Pharyngolaryngeal pain			

subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Pneumonitis			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Stridor			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Tracheomalacia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Choking			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract inflammation			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Postnasal drip			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Rhinitis seasonal			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			

Sleep disorder			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Crying			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0
Agitation			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Breath holding			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Screaming			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Tic			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	0	2	2
Weight decreased			

subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	2	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Cardiac murmur functional			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Head circumference abnormal			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Blood lead increased			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Body height below normal			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	3 / 483 (0.62%)
occurrences (all)	1	2	3
Fall			

subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	3 / 483 (0.62%)
occurrences (all)	0	2	3
Traumatic brain injury			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	2	1	1
Arthropod bite			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Excoriation			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	0	2	0
Head injury			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Accident			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Chemical burns of eye			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Corneal abrasion			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Lower limb fracture			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	2	0
Skin laceration			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Thermal burn			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase			

increased			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Animal bite			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Torus fracture			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Plagiocephaly			
subjects affected / exposed	9 / 486 (1.85%)	6 / 483 (1.24%)	11 / 483 (2.28%)
occurrences (all)	9	6	11
Dacryostenosis congenital			
subjects affected / exposed	2 / 486 (0.41%)	3 / 483 (0.62%)	1 / 483 (0.21%)
occurrences (all)	2	3	1
Hydrocele			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	2 / 483 (0.41%)
occurrences (all)	0	1	2
Macrocephaly			

subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	2	1	0
Pectus excavatum			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	2	0	0
Ankyloglossia congenital			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Atrial septal defect			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Brachycephaly			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Hemihypertrophy			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Hip dysplasia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Hypospadias			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Laryngomalacia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Naevus flammeus			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Phimosis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Pulmonary valve stenosis congenital			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Skull malformation			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	2
Ventricular septal defect			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Von Willebrand's disease			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Congenital naevus			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Tibial torsion			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Hypersomnia			
subjects affected / exposed	1 / 486 (0.21%)	2 / 483 (0.41%)	1 / 483 (0.21%)
occurrences (all)	1	2	1
Hypertonia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Convulsion			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Head titubation			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Hyporeflexia			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Hypotonia			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Poor quality sleep			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Psychomotor hyperactivity			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Subdural effusion			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Febrile convulsion			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Cerebral cyst			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Gross motor delay			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	4 / 483 (0.83%)
occurrences (all)	2	1	4
Leukocytosis			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0

Lymphadenopathy subjects affected / exposed occurrences (all)	2 / 486 (0.41%) 2	1 / 483 (0.21%) 1	0 / 483 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	1 / 486 (0.21%) 1	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Thrombocythaemia subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	6 / 486 (1.23%) 6	7 / 483 (1.45%) 7	6 / 483 (1.24%) 6
Middle ear effusion subjects affected / exposed occurrences (all)	1 / 486 (0.21%) 1	2 / 483 (0.41%) 2	4 / 483 (0.83%) 4
Cerumen impaction subjects affected / exposed occurrences (all)	2 / 486 (0.41%) 2	0 / 483 (0.00%) 0	2 / 483 (0.41%) 2
Otorrhoea subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	2 / 483 (0.41%) 2	0 / 483 (0.00%) 0
Deafness neurosensory subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
External ear inflammation subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Tympanic membrane disorder subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Tympanic membrane perforation			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Deafness			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	35 / 486 (7.20%)	37 / 483 (7.66%)	44 / 483 (9.11%)
occurrences (all)	38	39	46
Dacryostenosis acquired			
subjects affected / exposed	3 / 486 (0.62%)	3 / 483 (0.62%)	2 / 483 (0.41%)
occurrences (all)	3	3	2
Eye discharge			
subjects affected / exposed	4 / 486 (0.82%)	5 / 483 (1.04%)	2 / 483 (0.41%)
occurrences (all)	4	5	2
Strabismus			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Lacrimation increased			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	1 / 483 (0.21%)
occurrences (all)	0	2	1
Blepharitis			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0
Eye swelling			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Eyelid oedema			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Eyelid ptosis			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0
Dark circles under eyes			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0

Eye irritation			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Heterophoria			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Hypermetropia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Pupillary reflex impaired			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Pupils unequal			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Scleral disorder			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	44 / 486 (9.05%)	34 / 483 (7.04%)	56 / 483 (11.59%)
occurrences (all)	54	39	61
Vomiting			
subjects affected / exposed	26 / 486 (5.35%)	23 / 483 (4.76%)	30 / 483 (6.21%)
occurrences (all)	29	25	37
Constipation			
subjects affected / exposed	15 / 486 (3.09%)	31 / 483 (6.42%)	17 / 483 (3.52%)
occurrences (all)	16	34	18
Gastrooesophageal reflux disease			
subjects affected / exposed	28 / 486 (5.76%)	20 / 483 (4.14%)	18 / 483 (3.73%)
occurrences (all)	29	22	20
Teething			

subjects affected / exposed	5 / 486 (1.03%)	11 / 483 (2.28%)	9 / 483 (1.86%)
occurrences (all)	5	11	9
Infantile spitting up			
subjects affected / exposed	3 / 486 (0.62%)	5 / 483 (1.04%)	5 / 483 (1.04%)
occurrences (all)	3	5	6
Flatulence			
subjects affected / exposed	2 / 486 (0.41%)	6 / 483 (1.24%)	3 / 483 (0.62%)
occurrences (all)	2	7	3
Abdominal pain			
subjects affected / exposed	4 / 486 (0.82%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	4	2	3
Haematochezia			
subjects affected / exposed	3 / 486 (0.62%)	0 / 483 (0.00%)	5 / 483 (1.04%)
occurrences (all)	3	0	5
Stomach discomfort			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	3 / 483 (0.62%)
occurrences (all)	0	1	3
Umbilical hernia			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	1 / 483 (0.21%)
occurrences (all)	0	2	1
Abnormal faeces			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Anal fissure			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0
Colitis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	0	2	0
Frequent bowel movements			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Infantile colic			

subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	0	2	0
Mouth ulceration			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Abdominal discomfort			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Abdominal hernia			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Allergic colitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Dyschezia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Gingival cyst			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Gingival ulceration			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Mouth cyst			

subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Regurgitation			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Retching			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Tongue geographic			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Vomiting projectile			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Inguinal hernia			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Anal skin tags			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			

subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	45 / 486 (9.26%)	28 / 483 (5.80%)	42 / 483 (8.70%)
occurrences (all)	47	31	44
Dermatitis diaper			
subjects affected / exposed	34 / 486 (7.00%)	13 / 483 (2.69%)	30 / 483 (6.21%)
occurrences (all)	34	13	34
Rash			
subjects affected / exposed	22 / 486 (4.53%)	20 / 483 (4.14%)	18 / 483 (3.73%)
occurrences (all)	23	21	19
Seborrhoeic dermatitis			
subjects affected / exposed	12 / 486 (2.47%)	12 / 483 (2.48%)	11 / 483 (2.28%)
occurrences (all)	12	13	11
Dermatitis atopic			
subjects affected / exposed	9 / 486 (1.85%)	12 / 483 (2.48%)	15 / 483 (3.11%)
occurrences (all)	9	15	17
Dermatitis contact			
subjects affected / exposed	1 / 486 (0.21%)	11 / 483 (2.28%)	8 / 483 (1.66%)
occurrences (all)	1	11	8
Dermatitis			
subjects affected / exposed	5 / 486 (1.03%)	4 / 483 (0.83%)	9 / 483 (1.86%)
occurrences (all)	5	4	9
Seborrhoea			
subjects affected / exposed	1 / 486 (0.21%)	7 / 483 (1.45%)	7 / 483 (1.45%)
occurrences (all)	1	7	7
Heat rash			
subjects affected / exposed	4 / 486 (0.82%)	3 / 483 (0.62%)	8 / 483 (1.66%)
occurrences (all)	4	3	8
Dry skin			
subjects affected / exposed	2 / 486 (0.41%)	3 / 483 (0.62%)	8 / 483 (1.66%)
occurrences (all)	2	4	8
Rash papular			
subjects affected / exposed	4 / 486 (0.82%)	3 / 483 (0.62%)	5 / 483 (1.04%)
occurrences (all)	4	3	5

Dandruff			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	6 / 483 (1.24%)
occurrences (all)	2	2	6
Urticaria			
subjects affected / exposed	5 / 486 (1.03%)	4 / 483 (0.83%)	2 / 483 (0.41%)
occurrences (all)	5	4	2
Rash erythematous			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	4 / 483 (0.83%)
occurrences (all)	0	1	4
Rash macular			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	2	1	0
Acne infantile			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Drug eruption			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Intertrigo			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	1	0	2
Skin lesion			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	2	0	1
Acanthosis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Acne			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Ingrowing nail			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0

Post inflammatory pigmentation change			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Rash maculo-papular			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Skin disorder			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Cafe au lait spots			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Dermographism			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Eczema infantile			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Livedo reticularis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Nail discolouration			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Pityriasis alba			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Rash neonatal			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Rash vesicular			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Skin fissures			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Skin nodule			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Subcutaneous nodule			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Urticaria papular			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Keratosis pilaris			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Acrodermatitis			

subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Blister			
subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Dermal cyst			
subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Dermatitis acneiform			
subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Pityriasis rosea			
subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[25] occurrences (all)	262 / 420 (62.38%) 262	262 / 409 (64.06%) 262	250 / 400 (62.50%) 250
Tenderness (Significant) 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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[26] occurrences (all)	32 / 348 (9.20%) 32	35 / 337 (10.39%) 35	36 / 345 (10.43%) 36
Induration (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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[27] occurrences (all)	59 / 356 (16.57%) 59	68 / 347 (19.60%) 68	68 / 352 (19.32%) 68
Induration (Mild) 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 Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[28]	52 / 353 (14.73%)	58 / 344 (16.86%)	54 / 348 (15.52%)
occurrences (all)	52	58	54
Induration (Moderate) 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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[29]	12 / 338 (3.55%)	19 / 328 (5.79%)	17 / 340 (5.00%)
occurrences (all)	12	19	17
Erythema (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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[30]	69 / 355 (19.44%)	88 / 352 (25.00%)	83 / 360 (23.06%)
occurrences (all)	69	88	83
Erythema (Mild) 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: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[31]	64 / 354 (18.08%)	87 / 352 (24.72%)	76 / 358 (21.23%)
occurrences (all)	64	87	76
Erythema (Moderate) 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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[32]	7 / 334 (2.10%)	2 / 326 (0.61%)	8 / 337 (2.37%)
occurrences (all)	7	2	8
Tenderness (Any) Infant Series Dose 2	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: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[33]	235 / 354 (66.38%)	222 / 330 (67.27%)	219 / 337 (64.99%)
occurrences (all)	235	222	219
Tenderness (Significant) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[34]	26 / 269 (9.67%)	17 / 231 (7.36%)	32 / 262 (12.21%)
occurrences (all)	26	17	32
Induration (Any) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[35]	71 / 291 (24.40%)	56 / 248 (22.58%)	80 / 279 (28.67%)
occurrences (all)	71	56	80
Induration (Mild) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[36]	65 / 288 (22.57%)	54 / 246 (21.95%)	74 / 276 (26.81%)
occurrences (all)	65	54	74
Induration (Moderate) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[37]	11 / 270 (4.07%)	3 / 224 (1.34%)	12 / 255 (4.71%)
occurrences (all)	11	3	12
Erythema (Any) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[38]	88 / 292 (30.14%)	95 / 265 (35.85%)	97 / 281 (34.52%)
occurrences (all)	88	95	97
Erythema (Mild) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[39]	82 / 289 (28.37%)	91 / 263 (34.60%)	93 / 279 (33.33%)
occurrences (all)	82	91	93
Erythema (Moderate) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[40]	9 / 268 (3.36%)	4 / 223 (1.79%)	8 / 252 (3.17%)
occurrences (all)	9	4	8
Tenderness (Any) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[41]	198 / 317 (62.46%)	185 / 304 (60.86%)	165 / 300 (55.00%)
occurrences (all)	198	185	165
Tenderness (Significant) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[42]	22 / 248 (8.87%)	17 / 226 (7.52%)	24 / 237 (10.13%)
occurrences (all)	22	17	24
Induration (Any) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[43]	71 / 263 (27.00%)	59 / 250 (23.60%)	75 / 262 (28.63%)
occurrences (all)	71	59	75
Induration (Mild) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[44]	64 / 260 (24.62%)	56 / 249 (22.49%)	71 / 260 (27.31%)
occurrences (all)	64	56	71
Induration (Moderate) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[45]	10 / 242 (4.13%)	9 / 221 (4.07%)	9 / 229 (3.93%)
occurrences (all)	10	9	9
Erythema (Any) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[46]	110 / 278 (39.57%)	94 / 262 (35.88%)	103 / 274 (37.59%)
occurrences (all)	110	94	103
Erythema (Mild) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[47]	102 / 275 (37.09%)	88 / 260 (33.85%)	99 / 272 (36.40%)
occurrences (all)	102	88	99
Erythema (Moderate) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[48]	13 / 243 (5.35%)	9 / 219 (4.11%)	13 / 231 (5.63%)
occurrences (all)	13	9	13
Induration (Severe) Infant Series Dose 2	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 ^[49]	0 / 283 (0.00%)	0 / 221 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Urine odour abnormal			
subjects affected / exposed	0 / 486 (0.00%)	3 / 483 (0.62%)	0 / 483 (0.00%)
occurrences (all)	0	3	0
Dysuria			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Vesicoureteric reflux			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Renal tubular acidosis			

subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Endocrine disorders Precocious puberty subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Musculoskeletal and connective tissue disorders Torticollis subjects affected / exposed occurrences (all)	4 / 486 (0.82%) 4	2 / 483 (0.41%) 2	4 / 483 (0.83%) 4
Head deformity subjects affected / exposed occurrences (all)	2 / 486 (0.41%) 2	1 / 483 (0.21%) 1	0 / 483 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Muscle twitching subjects affected / exposed occurrences (all)	1 / 486 (0.21%) 1	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Knee deformity subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 486 (0.00%) 0	0 / 483 (0.00%) 0	0 / 483 (0.00%) 0
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	194 / 486 (39.92%) 254	187 / 483 (38.72%) 254	204 / 483 (42.24%) 268
Otitis media subjects affected / exposed occurrences (all)	142 / 486 (29.22%) 205	125 / 483 (25.88%) 164	135 / 483 (27.95%) 195
Bronchiolitis subjects affected / exposed occurrences (all)	72 / 486 (14.81%) 84	75 / 483 (15.53%) 83	66 / 483 (13.66%) 75
Nasopharyngitis			

subjects affected / exposed	31 / 486 (6.38%)	29 / 483 (6.00%)	28 / 483 (5.80%)
occurrences (all)	35	31	29
Gastroenteritis			
subjects affected / exposed	21 / 486 (4.32%)	32 / 483 (6.63%)	19 / 483 (3.93%)
occurrences (all)	22	32	20
Viral infection			
subjects affected / exposed	19 / 486 (3.91%)	18 / 483 (3.73%)	24 / 483 (4.97%)
occurrences (all)	20	19	27
Croup infectious			
subjects affected / exposed	16 / 486 (3.29%)	19 / 483 (3.93%)	18 / 483 (3.73%)
occurrences (all)	17	20	20
Candidiasis			
subjects affected / exposed	21 / 486 (4.32%)	14 / 483 (2.90%)	10 / 483 (2.07%)
occurrences (all)	21	16	12
Sinusitis			
subjects affected / exposed	16 / 486 (3.29%)	15 / 483 (3.11%)	11 / 483 (2.28%)
occurrences (all)	16	18	12
Otitis media acute			
subjects affected / exposed	14 / 486 (2.88%)	14 / 483 (2.90%)	15 / 483 (3.11%)
occurrences (all)	16	19	19
Rhinitis			
subjects affected / exposed	11 / 486 (2.26%)	16 / 483 (3.31%)	13 / 483 (2.69%)
occurrences (all)	11	18	13
Pharyngitis			
subjects affected / exposed	11 / 486 (2.26%)	10 / 483 (2.07%)	12 / 483 (2.48%)
occurrences (all)	14	10	12
Influenza			
subjects affected / exposed	9 / 486 (1.85%)	12 / 483 (2.48%)	4 / 483 (0.83%)
occurrences (all)	9	12	4
Intertrigo candida			
subjects affected / exposed	1 / 486 (0.21%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	1	2	0
Respiratory syncytial virus infection			
subjects affected / exposed	7 / 486 (1.44%)	7 / 483 (1.45%)	10 / 483 (2.07%)
occurrences (all)	7	7	10
Viral upper respiratory tract infection			

subjects affected / exposed	11 / 486 (2.26%)	11 / 483 (2.28%)	7 / 483 (1.45%)
occurrences (all)	12	12	7
Gastroenteritis viral			
subjects affected / exposed	10 / 486 (2.06%)	5 / 483 (1.04%)	9 / 483 (1.86%)
occurrences (all)	10	5	10
Pneumonia			
subjects affected / exposed	8 / 486 (1.65%)	6 / 483 (1.24%)	12 / 483 (2.48%)
occurrences (all)	8	6	12
Bronchitis			
subjects affected / exposed	6 / 486 (1.23%)	5 / 483 (1.04%)	10 / 483 (2.07%)
occurrences (all)	6	5	10
Candida nappy rash			
subjects affected / exposed	7 / 486 (1.44%)	5 / 483 (1.04%)	9 / 483 (1.86%)
occurrences (all)	7	5	9
Oral candidiasis			
subjects affected / exposed	9 / 486 (1.85%)	5 / 483 (1.04%)	6 / 483 (1.24%)
occurrences (all)	9	5	6
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	8 / 486 (1.65%)	6 / 483 (1.24%)	6 / 483 (1.24%)
occurrences (all)	8	6	6
Ear infection			
subjects affected / exposed	5 / 486 (1.03%)	5 / 483 (1.04%)	7 / 483 (1.45%)
occurrences (all)	7	5	9
Viral skin infection			
subjects affected / exposed	3 / 486 (0.62%)	7 / 483 (1.45%)	3 / 483 (0.62%)
occurrences (all)	3	7	3
Fungal skin infection			
subjects affected / exposed	6 / 486 (1.23%)	6 / 483 (1.24%)	0 / 483 (0.00%)
occurrences (all)	6	6	0
Urinary tract infection			
subjects affected / exposed	2 / 486 (0.41%)	3 / 483 (0.62%)	4 / 483 (0.83%)
occurrences (all)	2	3	4
Impetigo			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	2	2	2

Skin candida			
subjects affected / exposed	1 / 486 (0.21%)	4 / 483 (0.83%)	3 / 483 (0.62%)
occurrences (all)	1	4	3
Conjunctivitis bacterial			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	3 / 483 (0.62%)
occurrences (all)	1	1	3
Herpangina			
subjects affected / exposed	2 / 486 (0.41%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	2	2	2
Roseola			
subjects affected / exposed	0 / 486 (0.00%)	4 / 483 (0.83%)	2 / 483 (0.41%)
occurrences (all)	0	4	2
Acute sinusitis			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	2	0	1
Otitis externa			
subjects affected / exposed	5 / 486 (1.03%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	5	1	0
Cellulitis			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	2	0	0
Dacryocystitis			
subjects affected / exposed	0 / 486 (0.00%)	3 / 483 (0.62%)	1 / 483 (0.21%)
occurrences (all)	0	3	1
Conjunctivitis infective			
subjects affected / exposed	2 / 486 (0.41%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	2	1	1
Eye infection			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	2 / 483 (0.41%)
occurrences (all)	0	2	2
Respiratory tract infection viral			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Viral pharyngitis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	2 / 483 (0.41%)
occurrences (all)	0	2	2

Gastroenteritis rotavirus			
subjects affected / exposed	1 / 486 (0.21%)	2 / 483 (0.41%)	0 / 483 (0.00%)
occurrences (all)	1	2	0
Paronychia			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	1	1	1
Pneumonia viral			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Varicella			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	2 / 483 (0.41%)
occurrences (all)	0	1	2
Acarodermatitis			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	2	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 486 (0.21%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	1	1	0
Body tinea			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Dermatophytosis			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	2	0	0
Enteritis infectious			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Fungal infection			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Gastritis viral			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Hordeolum			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Periorbital cellulitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Pharyngitis streptococcal			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Rash pustular			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Staphylococcal infection			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	0	1	1
Tinea capitis			
subjects affected / exposed	2 / 486 (0.41%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	2	0	0
Tinea infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	0	0	2
Abscess oral			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Breast cellulitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Cellulitis staphylococcal			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0

Eczema herpeticum			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Eczema infected			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Erysipelas			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Furuncle			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Genital candidiasis			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Labyrinthitis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Parotitis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Perirectal abscess			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Pneumonia bacterial			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0

Pyelonephritis acute			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Scarlet fever			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Viraemia			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0

Chronic sinusitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 486 (0.00%)	2 / 483 (0.41%)	5 / 483 (1.04%)
occurrences (all)	0	2	5
Decreased appetite			
subjects affected / exposed	4 / 486 (0.82%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	4	0	2
Weight gain poor			

subjects affected / exposed	3 / 486 (0.62%)	0 / 483 (0.00%)	2 / 483 (0.41%)
occurrences (all)	3	0	2
Food intolerance			
subjects affected / exposed	3 / 486 (0.62%)	1 / 483 (0.21%)	1 / 483 (0.21%)
occurrences (all)	3	1	1
Feeding disorder neonatal			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	1	0	1
Cow's milk intolerance			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Increased appetite			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Lactose intolerance			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 486 (0.00%)	1 / 483 (0.21%)	0 / 483 (0.00%)
occurrences (all)	0	1	0
Oral intake reduced			
subjects affected / exposed	1 / 486 (0.21%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	1	0	0
Overweight			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	1 / 483 (0.21%)
occurrences (all)	0	0	1
Failure to thrive			
subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0
Underweight			

subjects affected / exposed	0 / 486 (0.00%)	0 / 483 (0.00%)	0 / 483 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Infant Series 7vPnC	After the Infant Series Combined 13vPnC	After the Infant Series 7vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	227 / 244 (93.03%)	88 / 1445 (6.09%)	11 / 244 (4.51%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Haemangioma of skin			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Benign penile neoplasm			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Lipoma			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Fibrous histiocytoma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Neonatal disorder			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Umbilical granuloma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	25 / 244 (10.25%)	38 / 1445 (2.63%)	9 / 244 (3.69%)
occurrences (all)	29	38	10
Irritability			
subjects affected / exposed	8 / 244 (3.28%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	11	0	0
Injection site erythema			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Injection site induration			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Injection site dryness			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Injection site haematoma			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Injection site urticaria			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Developmental delay			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ 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 Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[1]	45 / 173 (26.01%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	45	0	0
Fever >39°C but ≤40°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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	2 / 161 (1.24%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Fever >40°C Dose 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	1 / 160 (0.63%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	98 / 200 (49.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	98	0	0
Irritability 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[5]	198 / 226 (87.61%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	198	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[6]	154 / 212 (72.64%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	154	0	0
Decreased sleep Infant 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 Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[7] occurrences (all)	90 / 194 (46.39%) 90	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hives (urticaria) Infant 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	0 / 164 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Fever >39°C but ≤40°C Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	0 / 124 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Fever >40°C Dose Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all)	0 / 124 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Decreased appetite Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	81 / 164 (49.39%) 81	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Irritability Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all)	163 / 201 (81.09%) 163	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Increased sleep Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed ^[13]	112 / 177 (63.28%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	112	0	0
Decreased sleep Infant Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[14]	77 / 159 (48.43%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	77	0	0
Hives (urticaria) Infant Dose 2	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[15]	1 / 127 (0.79%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Fever ≥38°C but ≤39°C Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[16]	43 / 132 (32.58%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	43	0	0
Fever >39°C but ≤40°C Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[17]	7 / 113 (6.19%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	7	0	0
Fever >40°C Dose Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[18]	1 / 111 (0.90%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Decreased appetite Infant Series Dose 3	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 Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[19] occurrences (all)	72 / 144 (50.00%) 72	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Irritability Infant Series Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[20] occurrences (all)	157 / 186 (84.41%) 157	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Increased sleep Infant Series 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[21] occurrences (all)	71 / 138 (51.45%) 71	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Decreased sleep Infant Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[22] occurrences (all)	83 / 147 (56.46%) 83	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hives (urticaria) Infant Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[23] occurrences (all)	2 / 112 (1.79%) 2	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Fever ≥38°C but ≤39°C Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[24] occurrences (all)	40 / 143 (27.97%) 40	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Immune system disorders Milk allergy subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0

Drug hypersensitivity subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	4 / 1445 (0.28%) 4	0 / 244 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	4 / 1445 (0.28%) 4	1 / 244 (0.41%) 1
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	2 / 1445 (0.14%) 2	0 / 244 (0.00%) 0
Anaphylactic reaction subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Social circumstances Overfeeding of infant subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Reproductive system and breast disorders Vulval disorder subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Penile adhesion subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Balanitis subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Breast cyst subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Genital discomfort subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Gynaecomastia			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Genital rash			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	33 / 244 (13.52%)	0 / 1445 (0.00%)	1 / 244 (0.41%)
occurrences (all)	36	0	1
Nasal congestion			
subjects affected / exposed	15 / 244 (6.15%)	0 / 1445 (0.00%)	1 / 244 (0.41%)
occurrences (all)	16	0	1
Rhinorrhoea			
subjects affected / exposed	9 / 244 (3.69%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	10	1	0
Wheezing			
subjects affected / exposed	5 / 244 (2.05%)	3 / 1445 (0.21%)	0 / 244 (0.00%)
occurrences (all)	5	3	0
Bronchial hyperreactivity			
subjects affected / exposed	6 / 244 (2.46%)	6 / 1445 (0.42%)	2 / 244 (0.82%)
occurrences (all)	7	6	2
Sneezing			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Asthma			
subjects affected / exposed	1 / 244 (0.41%)	4 / 1445 (0.28%)	0 / 244 (0.00%)
occurrences (all)	1	4	0
Rhinitis allergic			

subjects affected / exposed	1 / 244 (0.41%)	10 / 1445 (0.69%)	2 / 244 (0.82%)
occurrences (all)	1	10	2
Sinus congestion			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Pulmonary congestion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Tracheomalacia			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Choking			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Postnasal drip			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Rhinitis seasonal			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Crying			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Breath holding			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Restlessness subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Screaming subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Tic subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Investigations Cardiac murmur subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Cardiac murmur functional subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Head circumference abnormal subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
White blood cell count increased			

subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Blood lead increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Body height below normal subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Traumatic brain injury subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Excoriation subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Head injury subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Accident subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Chemical burns of eye			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Corneal abrasion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Lower limb fracture			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Torus fracture subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Vaccination complication subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Congenital, familial and genetic disorders			
Plagiocephaly subjects affected / exposed occurrences (all)	5 / 244 (2.05%) 5	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Dacryostenosis congenital subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hydrocele subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Macrocephaly subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Pectus excavatum subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Ankyloglossia congenital subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Atrial septal defect subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Brachycephaly subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hemihypertrophy subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hip dysplasia			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Hypospadias			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Laryngomalacia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Naevus flammeus			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Phimosi			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve stenosis congenital			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skull malformation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Ventricular septal defect			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Von Willebrand's disease			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Congenital naevus			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Tibial torsion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	1 / 244 (0.41%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	1	1	0

Nervous system disorders			
Hypersomnia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Hypertonia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Head titubation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Hyporeflexia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	1 / 244 (0.41%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	1	1	0
Lethargy			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Subdural effusion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			

subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	2 / 1445 (0.14%) 2	0 / 244 (0.00%) 0
Cerebral cyst subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Speech disorder developmental subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Gross motor delay subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	2 / 1445 (0.14%) 2	0 / 244 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	2 / 244 (0.82%) 2	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Thrombocythaemia subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	8 / 244 (3.28%) 9	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Middle ear effusion			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Otorrhoea			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Deafness neurosensory			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
External ear inflammation			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane disorder			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	26 / 244 (10.66%)	0 / 1445 (0.00%)	1 / 244 (0.41%)
occurrences (all)	28	0	1
Dacryostenosis acquired			
subjects affected / exposed	4 / 244 (1.64%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	4	1	0
Eye discharge			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Strabismus			
subjects affected / exposed	2 / 244 (0.82%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	2	1	0

Lacrimation increased			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Dark circles under eyes			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Heterophoria			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Hypermetropia			
subjects affected / exposed	1 / 244 (0.41%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	1	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pupillary reflex impaired			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pupils unequal			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Scleral disorder			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	32 / 244 (13.11%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	36	1	0
Vomiting			
subjects affected / exposed	25 / 244 (10.25%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	30	0	0
Constipation			
subjects affected / exposed	17 / 244 (6.97%)	1 / 1445 (0.07%)	1 / 244 (0.41%)
occurrences (all)	18	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	10 / 244 (4.10%)	2 / 1445 (0.14%)	0 / 244 (0.00%)
occurrences (all)	10	2	0
Teething			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Infantile spitting up			
subjects affected / exposed	4 / 244 (1.64%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	4	0	0
Flatulence			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Haematochezia			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Stomach discomfort			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			

subjects affected / exposed	1 / 244 (0.41%)	2 / 1445 (0.14%)	1 / 244 (0.41%)
occurrences (all)	1	2	1
Abnormal faeces			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Allergic colitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Dyschezia			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Gingival cyst			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Gingival ulceration			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Mouth cyst			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Oral disorder			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Tongue geographic			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Vomiting projectile			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Anal skin tags			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	21 / 244 (8.61%)	12 / 1445 (0.83%)	1 / 244 (0.41%)
occurrences (all)	22	12	1
Dermatitis diaper			
subjects affected / exposed	13 / 244 (5.33%)	0 / 1445 (0.00%)	1 / 244 (0.41%)
occurrences (all)	14	0	1
Rash			
subjects affected / exposed	13 / 244 (5.33%)	3 / 1445 (0.21%)	0 / 244 (0.00%)
occurrences (all)	13	3	0
Seborrhoeic dermatitis			
subjects affected / exposed	12 / 244 (4.92%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	13	0	0
Dermatitis atopic			
subjects affected / exposed	9 / 244 (3.69%)	4 / 1445 (0.28%)	0 / 244 (0.00%)
occurrences (all)	10	4	0

Dermatitis contact			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Dermatitis			
subjects affected / exposed	4 / 244 (1.64%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	4	1	0
Seborrhoea			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Heat rash			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Rash papular			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Dandruff			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Urticaria			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Acne infantile			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0

Intertrigo			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Acanthosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Post inflammatory pigmentation change			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Skin irritation			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			

subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Dermographism			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eczema infantile			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pityriasis alba			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Rash neonatal			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skin fissures			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Skin nodule			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Subcutaneous nodule			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Keratosis pilaris			
subjects affected / exposed	0 / 244 (0.00%)	2 / 1445 (0.14%)	0 / 244 (0.00%)
occurrences (all)	0	2	0
Vitiligo			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Acrodermatitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose			
alternative dictionary used: Local Reactions 0.0	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 assessment type: Systematic			

subjects affected / exposed ^[25]	142 / 212 (66.98%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	142	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[26]	22 / 170 (12.94%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	22	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[27]	32 / 176 (18.18%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	32	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[28]	28 / 173 (16.18%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	28	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[29]	6 / 167 (3.59%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	6	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[30]	41 / 180 (22.78%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	41	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[31]	39 / 180 (21.67%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	39	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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[32]	2 / 164 (1.22%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Tenderness (Any) Infant Series Dose 2	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: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[33]	114 / 176 (64.77%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	114	0	0
Tenderness (Significant) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[34]	15 / 132 (11.36%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	15	0	0
Induration (Any) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[35]	25 / 141 (17.73%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	25	0	0
Induration (Mild) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[36]	25 / 141 (17.73%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	25	0	0
Induration (Moderate) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[37]	5 / 128 (3.91%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	5	0	0
Erythema (Any) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[38]	46 / 153 (30.07%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	46	0	0
Erythema (Mild) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[39]	44 / 153 (28.76%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	44	0	0
Erythema (Moderate) Infant Series Dose 2	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[40]	4 / 128 (3.13%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	4	0	0
Tenderness (Any) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[41]	101 / 156 (64.74%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	101	0	0
Tenderness (Significant) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[42]	14 / 118 (11.86%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	14	0	0
Induration (Any) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed ^[43]	39 / 128 (30.47%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	39	0	0
Induration (Mild) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[44]	37 / 127 (29.13%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	37	0	0
Induration (Moderate) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[45]	8 / 114 (7.02%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	8	0	0
Erythema (Any) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[46]	54 / 137 (39.42%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	54	0	0
Erythema (Mild) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[47]	52 / 135 (38.52%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	52	0	0
Erythema (Moderate) Infant Series Dose 3	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[48]	9 / 116 (7.76%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	9	0	0
Induration (Severe) Infant Series Dose 2	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 ^[49] occurrences (all)	0 / 127 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Renal and urinary disorders			
Urine odour abnormal subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	2 / 244 (0.82%) 2	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hydronephrosis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Vesicoureteric reflux subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	3 / 1445 (0.21%) 3	0 / 244 (0.00%) 0
Renal tubular acidosis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Endocrine disorders			
Precocious puberty subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Torticollis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 2	0 / 244 (0.00%) 0
Head deformity subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	2 / 244 (0.82%) 2	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Muscle twitching subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0

Knee deformity subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	97 / 244 (39.75%) 135	2 / 1445 (0.14%) 2	0 / 244 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	85 / 244 (34.84%) 131	4 / 1445 (0.28%) 4	0 / 244 (0.00%) 0
Bronchiolitis subjects affected / exposed occurrences (all)	44 / 244 (18.03%) 49	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	17 / 244 (6.97%) 19	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	15 / 244 (6.15%) 15	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	11 / 244 (4.51%) 13	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Croup infectious subjects affected / exposed occurrences (all)	8 / 244 (3.28%) 8	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Candidiasis subjects affected / exposed occurrences (all)	7 / 244 (2.87%) 7	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	10 / 244 (4.10%) 12	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Otitis media acute			

subjects affected / exposed	6 / 244 (2.46%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	11	0	0
Rhinitis			
subjects affected / exposed	6 / 244 (2.46%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	6	1	0
Pharyngitis			
subjects affected / exposed	7 / 244 (2.87%)	0 / 1445 (0.00%)	1 / 244 (0.41%)
occurrences (all)	7	0	1
Influenza			
subjects affected / exposed	8 / 244 (3.28%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	8	0	0
Intertrigo candida			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	7 / 244 (2.87%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	7	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis viral			
subjects affected / exposed	5 / 244 (2.05%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	5	0	0
Pneumonia			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	3 / 244 (1.23%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	3	1	0
Candida nappy rash			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Oral candidiasis			
subjects affected / exposed	4 / 244 (1.64%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	4	0	0
Respiratory syncytial virus			

bronchiolitis			
subjects affected / exposed	4 / 244 (1.64%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	4	0	0
Ear infection			
subjects affected / exposed	4 / 244 (1.64%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	5	0	0
Viral skin infection			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Impetigo			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Skin candida			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Herpangina			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Roseola			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Acute sinusitis			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Otitis externa			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	3 / 244 (1.23%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	3	0	0
Dacryocystitis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	2 / 244 (0.82%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	2	0	0
Viral pharyngitis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Varicella			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Beta haemolytic streptococcal infection			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Dermatophytosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Gastritis viral			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Tinea capitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Tinea infection			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Abscess oral			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Breast cellulitis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Eczema herpeticum			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Eczema infected			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis salmonella			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Perirectal abscess			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Rotavirus infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Viraemia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Otitis media chronic			
subjects affected / exposed	0 / 244 (0.00%)	3 / 1445 (0.21%)	0 / 244 (0.00%)
occurrences (all)	0	3	0
Coxsackie viral infection			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Chronic sinusitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Exanthema subitum subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Herpes virus infection subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Lyme disease subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	2 / 244 (0.82%) 2	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Weight gain poor subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Food intolerance subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	1 / 1445 (0.07%) 1	0 / 244 (0.00%) 0
Feeding disorder neonatal subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Cow's milk intolerance subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0	0 / 1445 (0.00%) 0	0 / 244 (0.00%) 0
Increased appetite			

subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	1 / 244 (0.41%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	1	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Oral intake reduced			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Overweight			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 244 (0.00%)	1 / 1445 (0.07%)	0 / 244 (0.00%)
occurrences (all)	0	1	0
Underweight			
subjects affected / exposed	0 / 244 (0.00%)	0 / 1445 (0.00%)	0 / 244 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Toddler Dose Combined 13vPnC	Toddler Dose 7vPnC	Post Toddler Dose 6- Month Follow-up Combined 13vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	906 / 1210 (74.88%)	152 / 208 (73.08%)	37 / 1443 (2.56%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Haemangioma of skin			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Melanocytic naevus			
subjects affected / exposed	1 / 1210 (0.08%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	1	1	0
Benign neoplasm			

subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Benign penile neoplasm subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Lipoma subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Fibrous histiocytoma subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Pregnancy, puerperium and perinatal conditions Cephalhaematoma subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Neonatal disorder subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Umbilical granuloma subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Irritability subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	3 / 1210 (0.25%) 3	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Injection site swelling			

subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Injection site pain			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences (all)	2	0	1
Injection site reaction			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Cyst			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Injection site dryness			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Injection site haematoma			

subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Injection site urticaria			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Developmental delay			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$ 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	192 / 667 (28.79%)	32 / 107 (29.91%)	0 / 1443 (0.00%)
occurrences (all)	192	32	0
Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$ 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	26 / 592 (4.39%)	5 / 95 (5.26%)	0 / 1443 (0.00%)
occurrences (all)	26	5	0
Fever $> 40^{\circ}\text{C}$ Dose 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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	6 / 586 (1.02%)	0 / 93 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	6	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 ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	410 / 790 (51.90%)	58 / 115 (50.43%)	0 / 1443 (0.00%)
occurrences (all)	410	58	0
Irritability Infant Series Dose 1 and	Additional description: Subjects affected and occurrences for SE is same as data		

<p>Toddler Dose</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p>	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	771 / 943 (81.76%)	128 / 160 (80.00%)	0 / 1443 (0.00%)
	771	128	0
<p>Increased sleep Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p>	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.		
	372 / 779 (47.75%)	60 / 126 (47.62%)	0 / 1443 (0.00%)
	372	60	0
<p>Decreased sleep Infant Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p>	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.		
	361 / 770 (46.88%)	50 / 117 (42.74%)	0 / 1443 (0.00%)
	361	50	0
<p>Hives (urticaria) Infant Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p>	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.		
	13 / 607 (2.14%)	5 / 96 (5.21%)	0 / 1443 (0.00%)
	13	5	0
<p>Fever >39°C but ≤40°C Infant Series Dose 2</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p>	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.		
	0 / 607 (0.00%)	0 / 96 (0.00%)	0 / 1443 (0.00%)
	0	0	0
<p>Fever >40°C Dose Infant Series Dose 2</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p>	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.		
	0 / 607 (0.00%)	0 / 96 (0.00%)	0 / 1443 (0.00%)
	0	0	0
<p>Decreased appetite Infant Series</p>	Additional description: Subjects affected and occurrences for SE is same as data		

Dose 2	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	0 / 607 (0.00%) 0	0 / 96 (0.00%) 0	0 / 1443 (0.00%) 0
Irritability Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all)	0 / 607 (0.00%) 0	0 / 96 (0.00%) 0	0 / 1443 (0.00%) 0
Increased sleep Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all)	0 / 607 (0.00%) 0	0 / 96 (0.00%) 0	0 / 1443 (0.00%) 0
Decreased sleep Infant Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[14] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Hives (urticaria) Infant Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Fever ≥38°C but ≤39°C Infant Series Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Fever >39°C but ≤40°C Infant	Additional description: Subjects affected and occurrences for SE is same as data		

Series Dose 3	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0
Fever >40°C Dose Infant Series Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0
Decreased appetite Infant Series Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0
Irritability Infant Series Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[20] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0
Increased sleep Infant Series 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[21] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0
Decreased sleep Infant Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[22] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0
Hives (urticaria) Infant Dose 3	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[23] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Fever ≥38°C but ≤39°C Infant Series Dose 2 alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[24] occurrences (all)	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.		
	0 / 1210 (0.00%) 0	0 / 143 (0.00%) 0	0 / 1443 (0.00%) 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Drug hypersensitivity			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	6 / 1443 (0.42%)
occurrences (all)	3	0	6
Food allergy			
subjects affected / exposed	4 / 1210 (0.33%)	0 / 208 (0.00%)	3 / 1443 (0.21%)
occurrences (all)	4	0	3
Hypersensitivity			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Anaphylactic reaction			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Overfeeding of infant			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Vulval disorder			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Penile adhesion			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Balanitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Breast cyst			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Genital discomfort			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Gynaecomastia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Genital rash			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Penile oedema			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	22 / 1210 (1.82%)	8 / 208 (3.85%)	0 / 1443 (0.00%)
occurrences (all)	23	8	0
Nasal congestion			
subjects affected / exposed	5 / 1210 (0.41%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	6	0	0
Rhinorrhoea			

subjects affected / exposed	22 / 1210 (1.82%)	5 / 208 (2.40%)	0 / 1443 (0.00%)
occurrences (all)	22	5	0
Wheezing			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences (all)	3	0	1
Bronchial hyperreactivity			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	2 / 1443 (0.14%)
occurrences (all)	1	0	2
Sneezing			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	3 / 1210 (0.25%)	1 / 208 (0.48%)	10 / 1443 (0.69%)
occurrences (all)	4	1	10
Rhinitis allergic			
subjects affected / exposed	4 / 1210 (0.33%)	1 / 208 (0.48%)	4 / 1443 (0.28%)
occurrences (all)	4	1	4
Sinus congestion			
subjects affected / exposed	2 / 1210 (0.17%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	2	1	0
Pulmonary congestion			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tracheomalacia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Choking			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Postnasal drip			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rhinitis seasonal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0

Crying subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Agitation subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Breath holding subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Initial insomnia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Restlessness subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Screaming subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Tic subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	1 / 1443 (0.07%) 1
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Investigations Cardiac murmur subjects affected / exposed occurrences (all)	6 / 1210 (0.50%) 6	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur functional			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Head circumference abnormal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Blood lead increased			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Body height below normal			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Liver function test abnormal			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 1210 (0.08%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	1	1	0
Fall			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Traumatic brain injury			

subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	3 / 1210 (0.25%)	2 / 208 (0.96%)	0 / 1443 (0.00%)
occurrences (all)	3	2	0
Excoriation			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Head injury			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Accident			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Chemical burns of eye			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Corneal abrasion			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Lower limb fracture			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Thermal burn			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0

Animal bite			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Arthropod sting			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Burns second degree			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Joint sprain			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Mouth injury			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Torus fracture			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Vaccination complication			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Plagiocephaly			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis congenital			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Macrocephaly			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Pectus excavatum			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Ankyloglossia congenital			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Atrial septal defect			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Brachycephaly			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hemihypertrophy			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hip dysplasia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hypospadias			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Laryngomalacia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Naevus flammeus			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Phimosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve stenosis congenital			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Skull malformation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Ventricular septal defect			

subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Von Willebrand's disease subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Congenital naevus subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Tibial torsion subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Cardiac disorders Cyanosis subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Nervous system disorders Hypersomnia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Hypertonia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Convulsion subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Head titubation subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Hyporeflexia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Hypotonia subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Lethargy			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Subdural effusion			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Cerebral cyst			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Gross motor delay			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 1210 (0.33%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	4	1	0
Leukocytosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences (all)	1	0	1

Lymphadenitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Thrombocythaemia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	4 / 1210 (0.33%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	4	1	0
Middle ear effusion			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Cerumen impaction			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Otorrhoea			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Deafness neurosensory			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane disorder			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Deafness			

subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	17 / 1210 (1.40%)	3 / 208 (1.44%)	0 / 1443 (0.00%)
occurrences (all)	17	3	0
Dacryostenosis acquired			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Eye discharge			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Strabismus			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Blepharitis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Eye swelling			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dark circles under eyes			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0

Heterophoria			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hypermetropia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pupillary reflex impaired			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pupils unequal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Scleral disorder			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	37 / 1210 (3.06%)	8 / 208 (3.85%)	0 / 1443 (0.00%)
occurrences (all)	37	8	0
Vomiting			
subjects affected / exposed	17 / 1210 (1.40%)	4 / 208 (1.92%)	0 / 1443 (0.00%)
occurrences (all)	17	4	0
Constipation			
subjects affected / exposed	3 / 1210 (0.25%)	3 / 208 (1.44%)	0 / 1443 (0.00%)
occurrences (all)	3	3	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Teething			
subjects affected / exposed	7 / 1210 (0.58%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	7	1	0
Infantile spitting up			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Stomach discomfort			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Anal fissure			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Allergic colitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dyschezia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Gingival cyst			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Gingival ulceration			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Mouth cyst			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Regurgitation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tongue geographic			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Vomiting projectile			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Anal skin tags			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			

Eczema			
subjects affected / exposed	17 / 1210 (1.40%)	0 / 208 (0.00%)	6 / 1443 (0.42%)
occurrences (all)	17	0	6
Dermatitis diaper			
subjects affected / exposed	31 / 1210 (2.56%)	5 / 208 (2.40%)	0 / 1443 (0.00%)
occurrences (all)	31	5	0
Rash			
subjects affected / exposed	27 / 1210 (2.23%)	2 / 208 (0.96%)	0 / 1443 (0.00%)
occurrences (all)	27	2	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	4 / 1210 (0.33%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	4	1	0
Dermatitis contact			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	1 / 1210 (0.08%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	1	1	0
Seborrhoea			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Dandruff			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0

Urticaria			
subjects affected / exposed	6 / 1210 (0.50%)	2 / 208 (0.96%)	0 / 1443 (0.00%)
occurrences (all)	6	2	0
Rash erythematous			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Acne infantile			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Acanthosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Post inflammatory pigmentation change			

subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Skin disorder			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Cafe au lait spots			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Dermographism			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Eczema infantile			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Livedo reticularis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pityriasis alba			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Psoriasis			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rash neonatal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Skin fissures			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Skin nodule			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Subcutaneous nodule			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Keratosis pilaris			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Acrodermatitis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Blister			

subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Pityriasis rosea			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	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 ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[25]	473 / 826 (57.26%)	83 / 131 (63.36%)	0 / 1443 (0.00%)
occurrences (all)	473	83	0
Tenderness (Significant) 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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[26]	42 / 630 (6.67%)	4 / 97 (4.12%)	0 / 1443 (0.00%)
occurrences (all)	42	4	0
Induration (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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[27]	220 / 698 (31.52%)	48 / 110 (43.64%)	0 / 1443 (0.00%)
occurrences (all)	220	48	0
Induration (Mild) 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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[28]	199 / 689 (28.88%)	44 / 107 (41.12%)	0 / 1443 (0.00%)
occurrences (all)	199	44	0
Induration (Moderate) Infant Series	Additional description: Subjects affected and occurrences for LR is same as data		

Dose 1 and Toddler Dose	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[29] occurrences (all)	53 / 627 (8.45%) 53	18 / 101 (17.82%) 18 0 / 1443 (0.00%) 0
Erythema (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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[30] occurrences (all)	319 / 749 (42.59%) 319	64 / 121 (52.89%) 64 0 / 1443 (0.00%) 0
Erythema (Mild) 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: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[31] occurrences (all)	288 / 735 (39.18%) 288	58 / 116 (50.00%) 58 0 / 1443 (0.00%) 0
Erythema (Moderate) 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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[32] occurrences (all)	67 / 631 (10.62%) 67	22 / 104 (21.15%) 22 0 / 1443 (0.00%) 0
Tenderness (Any) Infant Series Dose 2	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: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[33] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0 0 / 1443 (0.00%) 0
Tenderness (Significant) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[34] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0 0 / 1443 (0.00%) 0
Induration (Any) Infant Series Dose	Additional description: Subjects affected and occurrences for LR is same as data		

2	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.			
	alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[35] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Induration (Mild) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[36] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Induration (Moderate) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[37] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Erythema (Any) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[38] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Erythema (Mild) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[39] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Erythema (Moderate) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[40] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Tenderness (Any) Infant Series Dose	Additional description: Subjects affected and occurrences for LR is same as data			

3	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.			
	alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[41] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Tenderness (Significant) Infant Series Dose 3	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[42] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Induration (Any) Infant Series Dose 3	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[43] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Induration (Mild) Infant Series Dose 3	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[44] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Induration (Moderate) Infant Series Dose 3	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[45] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Erythema (Any) Infant Series Dose 3	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[46] occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Erythema (Mild) Infant Series Dose 3	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.			
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[47]</p> <p>occurrences (all)</p>	<p>0 / 1210 (0.00%)</p> <p>0</p>	<p>0 / 208 (0.00%)</p> <p>0</p>	<p>0 / 1443 (0.00%)</p> <p>0</p>
Erythema (Moderate) Infant Series Dose 3	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.		
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[48]</p> <p>occurrences (all)</p>	<p>0 / 1210 (0.00%)</p> <p>0</p>	<p>0 / 208 (0.00%)</p> <p>0</p>	<p>0 / 1443 (0.00%)</p> <p>0</p>
Induration (Severe) Infant Series Dose 2	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		
<p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[49]</p> <p>occurrences (all)</p>	<p>0 / 1210 (0.00%)</p> <p>0</p>	<p>0 / 208 (0.00%)</p> <p>0</p>	<p>0 / 1443 (0.00%)</p> <p>0</p>
Renal and urinary disorders			
Urine odour abnormal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Vesicoureteric reflux			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Renal tubular acidosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Precocious puberty subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	1 / 1443 (0.07%) 1
Musculoskeletal and connective tissue disorders			
Torticollis subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Head deformity subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Muscle twitching subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Knee deformity subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	62 / 1210 (5.12%) 62	11 / 208 (5.29%) 11	0 / 1443 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	70 / 1210 (5.79%) 72	20 / 208 (9.62%) 20	1 / 1443 (0.07%) 1
Bronchiolitis subjects affected / exposed occurrences (all)	2 / 1210 (0.17%) 2	1 / 208 (0.48%) 1	0 / 1443 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	12 / 1210 (0.99%) 12	1 / 208 (0.48%) 1	0 / 1443 (0.00%) 0
Gastroenteritis			

subjects affected / exposed	16 / 1210 (1.32%)	3 / 208 (1.44%)	0 / 1443 (0.00%)
occurrences (all)	16	3	0
Viral infection			
subjects affected / exposed	20 / 1210 (1.65%)	6 / 208 (2.88%)	0 / 1443 (0.00%)
occurrences (all)	20	6	0
Croup infectious			
subjects affected / exposed	10 / 1210 (0.83%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	10	0	0
Candidiasis			
subjects affected / exposed	2 / 1210 (0.17%)	2 / 208 (0.96%)	0 / 1443 (0.00%)
occurrences (all)	2	2	0
Sinusitis			
subjects affected / exposed	12 / 1210 (0.99%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	12	0	0
Otitis media acute			
subjects affected / exposed	8 / 1210 (0.66%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	8	0	0
Rhinitis			
subjects affected / exposed	11 / 1210 (0.91%)	2 / 208 (0.96%)	0 / 1443 (0.00%)
occurrences (all)	11	2	0
Pharyngitis			
subjects affected / exposed	11 / 1210 (0.91%)	4 / 208 (1.92%)	0 / 1443 (0.00%)
occurrences (all)	11	4	0
Influenza			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Intertrigo candida			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Gastroenteritis viral			

subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Bronchitis			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Candida nappy rash			
subjects affected / exposed	2 / 1210 (0.17%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	2	1	0
Oral candidiasis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	5 / 1210 (0.41%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	5	0	0
Viral skin infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Urinary tract infection			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Skin candida			
subjects affected / exposed	2 / 1210 (0.17%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	2	1	0

Conjunctivitis bacterial subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Herpangina subjects affected / exposed occurrences (all)	5 / 1210 (0.41%) 5	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Roseola subjects affected / exposed occurrences (all)	4 / 1210 (0.33%) 4	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Acute sinusitis subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Otitis externa subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	2 / 1210 (0.17%) 2	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Dacryocystitis subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Conjunctivitis infective subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	1 / 208 (0.48%) 1	0 / 1443 (0.00%) 0
Eye infection subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Respiratory tract infection viral subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Viral pharyngitis subjects affected / exposed occurrences (all)	1 / 1210 (0.08%) 1	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0
Gastroenteritis rotavirus subjects affected / exposed occurrences (all)	0 / 1210 (0.00%) 0	0 / 208 (0.00%) 0	0 / 1443 (0.00%) 0

Paronychia			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Pneumonia viral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Acarodermatitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Fungal infection			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Gastritis viral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Periorbital cellulitis			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	3 / 1210 (0.25%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	3	1	0
Rash pustular			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	3 / 1210 (0.25%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	3	0	0
Tinea capitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tinea infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Abscess oral			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Breast cellulitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Eczema herpeticum			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0

Eczema infected			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	1 / 1210 (0.08%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	1	1	0
Folliculitis			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Labyrinthitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Perirectal abscess			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Viraemia			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	2 / 1443 (0.14%)
occurrences (all)	1	0	2
Coxsackie viral infection			
subjects affected / exposed	2 / 1210 (0.17%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	2	1	0
Chronic sinusitis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0

Viral rash			
subjects affected / exposed	11 / 1210 (0.91%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	11	1	0
Dermatitis infected			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Adenovirus infection			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Lyme disease			
subjects affected / exposed	0 / 1210 (0.00%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 1210 (0.08%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	1 / 1210 (0.08%)	1 / 208 (0.48%)	0 / 1443 (0.00%)
occurrences (all)	1	1	0
Food intolerance			

subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Feeding disorder neonatal			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Cow's milk intolerance			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Oral intake reduced			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Overweight			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 1210 (0.00%)	0 / 208 (0.00%)	1 / 1443 (0.07%)
occurrences (all)	0	0	1
Underweight			
subjects affected / exposed	2 / 1210 (0.17%)	0 / 208 (0.00%)	0 / 1443 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Post Toddler Dose 6- Month Follow-up 7vPnC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 244 (3.69%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Haemangioma of skin			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Benign neoplasm			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Benign penile neoplasm			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lipoma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Fibrous histiocytoma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Neonatal disorder			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Umbilical granuloma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site swelling			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site induration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Xerosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cyst			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site bruising			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site dryness			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site haemorrhage			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site haematoma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injection site urticaria			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Developmental delay			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Fever ≥38°C but ≤39°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 Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	0 / 244 (0.00%)		
occurrences (all)	0		
Fever >39°C but ≤40°C Infant	Additional description: Subjects affected and occurrences for SE is same as data		

Series Dose 1 and Toddler Dose	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[2] occurrences (all)	0 / 244 (0.00%) 0		
Fever >40°C Dose 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	0 / 244 (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 ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	0 / 244 (0.00%) 0		
Irritability 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all)	0 / 244 (0.00%) 0		
Increased sleep 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all)	0 / 244 (0.00%) 0		
Decreased sleep Infant 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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all)	0 / 244 (0.00%) 0		
Hives (urticaria) Infant Dose 1 and	Additional description: Subjects affected and occurrences for SE is same as data		

Toddler Dose	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all)	0 / 244 (0.00%) 0		
Fever >39°C but ≤40°C Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all)	0 / 244 (0.00%) 0		
Fever >40°C Dose Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all)	0 / 244 (0.00%) 0		
Decreased appetite Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all)	0 / 244 (0.00%) 0		
Irritability Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all)	0 / 244 (0.00%) 0		
Increased sleep Infant Series Dose 2	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 Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all)	0 / 244 (0.00%) 0		
Decreased sleep Infant Dose 2	Additional description: Subjects affected and occurrences for SE is same as data		

<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[14]</p> <p>occurrences (all)</p>	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
	0 / 244 (0.00%)		
Hives (urticaria) Infant Dose 2	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[15]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Fever ≥38°C but ≤39°C Infant Series Dose 3	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[16]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Fever >39°C but ≤40°C Infant Series Dose 3	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[17]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Fever >40°C Dose Infant Series Dose 3	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[18]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Decreased appetite Infant Series Dose 3	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[19]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Irritability Infant Series Dose 3	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.			
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[20]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Increased sleep Infant Series 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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[21]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Decreased sleep Infant Dose 3	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[22]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Hives (urticaria) Infant Dose 3	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[23]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Fever ≥38°C but ≤39°C Infant Series Dose 2	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.		
<p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[24]</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		
Immune system disorders			
<p>Milk allergy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	1 / 244 (0.41%)		
<p>Drug hypersensitivity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	0 / 244 (0.00%)		

Food allergy			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	1		
Hypersensitivity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Anaphylactic reaction			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Social circumstances			
Overfeeding of infant			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Vulval disorder			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Penile adhesion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Balanitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Breast cyst			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Genital discomfort			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gynaecomastia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Genital labial adhesions			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Genital rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Penile oedema			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Bronchial hyperreactivity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	1		
Sinus congestion			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pulmonary congestion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Bronchospasm			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dysphonia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Upper respiratory tract congestion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Stridor			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tracheomalacia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Choking			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lower respiratory tract inflammation			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Postnasal drip			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rhinitis seasonal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rhonchi			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Crying			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Agitation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Breath holding			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Initial insomnia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Screaming subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Tic subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Investigations Cardiac murmur subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Weight decreased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Cardiac murmur functional subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Head circumference abnormal subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Weight increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Blood lead increased			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Body height below normal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Liver function test abnormal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Traumatic brain injury			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Excoriation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Head injury			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Accident			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Chemical burns of eye			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Concussion			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Corneal abrasion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lower limb fracture			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Thermal burn			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Animal bite			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Arthropod sting			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Burns second degree			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Joint sprain			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Mouth injury			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Torus fracture			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Vaccination complication subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Congenital, familial and genetic disorders			
Plagiocephaly subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Dacryostenosis congenital subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Hydrocele subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Macrocephaly subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Pectus excavatum subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Ankyloglossia congenital subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Atrial septal defect subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Brachycephaly subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Hemihypertrophy subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Hip dysplasia subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Hypospadias			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Laryngomalacia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Naevus flammeus			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Phimosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pulmonary valve stenosis congenital			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skull malformation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Ventricular septal defect			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Von Willebrand's disease			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Congenital naevus			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tibial torsion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Hypersomnia			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hypertonia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Convulsion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Head titubation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hyporeflexia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hypotonia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Poor quality sleep			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Psychomotor hyperactivity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Subdural effusion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Febrile convulsion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cerebral cyst			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Speech disorder developmental			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gross motor delay			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lymphadenitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Thrombocythaemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	2		
Middle ear effusion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cerumen impaction			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Otorrhoea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Deafness neurosensory			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
External ear inflammation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tympanic membrane disorder			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Deafness			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dacryostenosis acquired			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eye discharge			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Strabismus			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Blepharitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eye swelling			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eyelid ptosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dark circles under eyes			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Heterophoria			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hypermetropia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Ocular hyperaemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pupillary reflex impaired			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pupils unequal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Scleral disorder			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	1		
Teething			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Infantile spitting up			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Stomach discomfort			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Umbilical hernia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Abnormal faeces			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Colitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Frequent bowel movements			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Infantile colic			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Abdominal discomfort			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Abdominal hernia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Allergic colitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dyschezia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Enteritis			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gingival cyst			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gingival ulceration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Mouth cyst			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Oral disorder			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Regurgitation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Retching			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tongue discolouration			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tongue geographic			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Vomiting projectile			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Inguinal hernia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Anal skin tags			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Aphthous stomatitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	4 / 244 (1.64%)		
occurrences (all)	4		
Dermatitis diaper			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	1		
Dermatitis atopic			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Dermatitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Seborrhoea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Heat rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash papular			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dandruff			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash erythematous			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash macular			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acne infantile			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Drug eruption			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Intertrigo			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Skin lesion			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acanthosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acne			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Ingrowing nail			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Post inflammatory pigmentation change			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin disorder			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin irritation			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cafe au lait spots			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermographism			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eczema infantile			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Livedo reticularis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Nail discolouration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pityriasis alba			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Purpura			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash neonatal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash vesicular			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin fissures			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin nodule			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Subcutaneous nodule			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Urticaria papular			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Keratosis pilaris			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Vitiligo			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acrodermatitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Blister			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermal cyst			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermatitis acneiform			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pityriasis rosea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	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 Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed ^[25]	0 / 244 (0.00%)		
occurrences (all)	0		
Tenderness (Significant) Infant	Additional description: Subjects affected and occurrences for LR is same as data		

Series Dose 1 and Toddler Dose	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[26] occurrences (all)	0 / 244 (0.00%)	0	
Induration (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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[27] occurrences (all)	0 / 244 (0.00%)	0	
Induration (Mild) 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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[28] occurrences (all)	0 / 244 (0.00%)	0	
Induration (Moderate) 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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[29] occurrences (all)	0 / 244 (0.00%)	0	
Erythema (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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[30] occurrences (all)	0 / 244 (0.00%)	0	
Erythema (Mild) 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: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[31] occurrences (all)	0 / 244 (0.00%)	0	
Erythema (Moderate) Infant Series	Additional description: Subjects affected and occurrences for LR is same as data		

Dose 1 and Toddler Dose	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[32] occurrences (all)	0 / 244 (0.00%)	0	
Tenderness (Any) Infant Series Dose 2	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: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[33] occurrences (all)	0 / 244 (0.00%)	0	
Tenderness (Significant) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[34] occurrences (all)	0 / 244 (0.00%)	0	
Induration (Any) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[35] occurrences (all)	0 / 244 (0.00%)	0	
Induration (Mild) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[36] occurrences (all)	0 / 244 (0.00%)	0	
Induration (Moderate) Infant Series Dose 2	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 Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[37] occurrences (all)	0 / 244 (0.00%)	0	
Erythema (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LR is same as data		

<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[38]</p> <p>occurrences (all)</p>		collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.	
Erythema (Mild) Infant Series Dose 2		0 / 244 (0.00%)	0
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[39]</p> <p>occurrences (all)</p>		0 / 244 (0.00%)	0
Erythema (Moderate) Infant Series Dose 2		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.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[40]</p> <p>occurrences (all)</p>		0 / 244 (0.00%)	0
Tenderness (Any) Infant Series Dose 3		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.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[41]</p> <p>occurrences (all)</p>		0 / 244 (0.00%)	0
Tenderness (Significant) Infant Series Dose 3		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.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[42]</p> <p>occurrences (all)</p>		0 / 244 (0.00%)	0
Induration (Any) Infant Series Dose 3		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.	
<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[43]</p> <p>occurrences (all)</p>		0 / 244 (0.00%)	0
Induration (Mild) Infant Series Dose		Additional description: Subjects affected and occurrences for LR is same as data	

3	<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[44]</p> <p>occurrences (all)</p>	<p>collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.</p> <p>0 / 244 (0.00%)</p> <p>0</p>
Induration (Moderate) Infant Series Dose 3	<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[45]</p> <p>occurrences (all)</p>	<p>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.</p> <p>0 / 244 (0.00%)</p> <p>0</p>
Erythema (Any) Infant Series Dose 3	<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[46]</p> <p>occurrences (all)</p>	<p>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.</p> <p>0 / 244 (0.00%)</p> <p>0</p>
Erythema (Mild) Infant Series Dose 3	<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[47]</p> <p>occurrences (all)</p>	<p>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.</p> <p>0 / 244 (0.00%)</p> <p>0</p>
Erythema (Moderate) Infant Series Dose 3	<p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[48]</p> <p>occurrences (all)</p>	<p>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.</p> <p>0 / 244 (0.00%)</p> <p>0</p>
Induration (Severe) Infant Series Dose 2	<p>alternative dictionary used: Local Reaction 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[49]</p> <p>occurrences (all)</p>	<p>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</p> <p>0 / 244 (0.00%)</p> <p>0</p>

Renal and urinary disorders			
Urine odour abnormal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Vesicoureteric reflux			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Renal tubular acidosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Precocious puberty			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Torticollis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Head deformity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Foot deformity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Muscle twitching			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Knee deformity			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Pain in extremity subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1		
Otitis media subjects affected / exposed occurrences (all)	1 / 244 (0.41%) 1		
Bronchiolitis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Viral infection subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Croup infectious subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Candidiasis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Sinusitis subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Otitis media acute subjects affected / exposed occurrences (all)	0 / 244 (0.00%) 0		
Rhinitis			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Intertrigo candida			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Candida nappy rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Ear infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Viral skin infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Fungal skin infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Impetigo			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Skin candida			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Conjunctivitis bacterial			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Herpangina			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Roseola			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acute sinusitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Otitis externa			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Dacryocystitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Conjunctivitis infective			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Respiratory tract infection viral			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Viral pharyngitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Paronychia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pneumonia viral			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Varicella			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acarodermatitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Body tinea			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermatophytosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Enteritis infectious			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Fungal infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gastritis viral			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Periorbital cellulitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rash pustular			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Staphylococcal infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tinea capitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tinea infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Abscess oral			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Breast cellulitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cellulitis staphylococcal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Diarrhoea infectious			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eczema herpeticum			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Eczema infected			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Erysipelas			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Erythema infectiosum			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Furuncle			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Gastroenteritis salmonella			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Genital candidiasis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Labyrinthitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Parotitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Perirectal abscess			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pneumonia bacterial			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Pyelonephritis acute			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Rotavirus infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Scarlet fever			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Staphylococcal skin infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Viraemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Viral diarrhoea			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Wound infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Otitis media chronic			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Coxsackie viral infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Chronic sinusitis			
subjects affected / exposed	1 / 244 (0.41%)		
occurrences (all)	1		
Viral rash			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Dermatitis infected			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Acute tonsillitis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Adenovirus infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Exanthema subitum			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		

Herpes virus infection			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lyme disease			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Weight gain poor			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Food intolerance			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Feeding disorder neonatal			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Cow's milk intolerance			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Increased appetite			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Lactose intolerance			

subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Metabolic acidosis			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Oral intake reduced			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Overweight			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Failure to thrive			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	0		
Underweight			
subjects affected / exposed	0 / 244 (0.00%)		
occurrences (all)	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.

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[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.

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[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.

[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.

[44] - 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.

[45] - 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.

[46] - 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.

[47] - 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.

[48] - 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.

[49] - 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
24 August 2007	Clarified that parent(s)/legal guardian(s) should contact the investigator by telephone if they suspected their child had hives, to determine whether the rash was likely to be urticaria.
11 March 2008	1. Interim safety analysis was to be performed following the infant phase of the study. 2. Toddler dose of Hib vaccine was removed from the study vaccinations given at the 12-month visit (visit 5)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported