Clinical trial results:
A Phase 3, Randomized, Active-Controlled, Double-Blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of Manufacturing Scale 13-valent Pneumococcal Conjugate Vaccine

Summary

EudraCT number	2006-006204-11
Trial protocol	PL
Global end of trial date	18 September 2008

Results information

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

Trial information

Trial identification

Sponsor protocol code	6096A1-3000

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00464945
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer, Inc., Pfizer ClinicalTrials.gov Call Center, 1 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer, Inc., Pfizer ClinicalTrials.gov Call Center, 1 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000036-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	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	12 January 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 September 2008
Global end of trial reached?	Yes
Global end of trial date	18 September 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objective:
To assess the pneumococcal immune responses induced by manufacturing scale 13-valent pneumococcal conjugate vaccine (13vPnC) relative to the immune responses induced by pilot scale 13vPnC when measured 1month after the infant series.
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	29 June 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	Poland: 269
Worldwide total number of subjects	269
EEA total number of subjects	269

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)	269
Children (2-11 years)	0
Adolescents (12-17 years)	0

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

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited in Poland from June 2007 to August 2007.

Pre-assignment

Screening details:

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

Period 1

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

Arms

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

Arm description:

Subjects received manufacturing scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

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

Dosage and administration details:

Single 0.5mL manufacturing scale dose of 13vPnC administered at 2, 3, 4 months (infant series).

Investigational medicinal product name	DTaP-IPV-Hib
Investigational medicinal product code	
Other name	Pentaxim
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

DTaP-IPV-Hib administered at 2, 3, 4 months (infant series).

Investigational medicinal product name	HBV
Investigational medicinal product code	
Other name	Engerix-B
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

HBV administered at month 2 (infant series).

Arm title	13vPnC Pilot Infant Series

Arm description:

Subjects received pilot scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and

hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

Arm type	Active comparator
Investigational medicinal product name	13vPnC Pilot Scale
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single 0.5mL pilot scale dose of 13vPnC administered at 2, 3, 4 months (infant series).

Investigational medicinal product name	DTaP-IPV-Hib
Investigational medicinal product code	
Other name	Pentaxim
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

DTaP-IPV-Hib administered at 2, 3, 4 months (infant series).

Investigational medicinal product name	HBV
Investigational medicinal product code	
Other name	Engerix-B
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

HBV administered at month 2 (infant series).

Number of subjects in period 1	13vPnC Manufacturing Infant Series	13vPnC Pilot Infant Series
Started	135	134
Vaccinated Dose 1	134	134
Vaccinated Dose 3	132	133
Vaccinated Dose 2	132	133
Completed	131	133
Not completed	4	1
Protocol Violation	1	-
Lost to follow-up	1	-
Withdrawal by parent/guardian request	2	1

Period 2

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

Arms

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

Arm description:

Included subjects who received manufacturing scale dose of 13vPnC coadministered with combined DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1) and manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	13vPnC Pilot After Infant Series

Arm description:

Included subjects who received pilot scale dose of 13vPnC coadministered with combined DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1) and pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC Manufacturing After Infant Series	13vPnC Pilot After Infant Series
Started	131	133
Completed	131	131
Not completed	0	2
Consent withdrawn by subject	-	2

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

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.3
upper limit	13.8

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 9V
Statistical analysis description: For serotype 9V the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	7.3

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 14
Statistical analysis description: For serotype 14 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.2
upper limit	4.7

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 18C
Statistical analysis description: For serotype 18C the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series

Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	9.2

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19F
Statistical analysis description: For serotype 19F the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	5.1

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 23F
Statistical analysis description: For serotype 23F the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.4
upper limit	10.6

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 1
Statistical analysis description:	
For serotype 1 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	9.2

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 3
Statistical analysis description:	
For serotype 3 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	4.2

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 5
Statistical analysis description:	
For serotype 5 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	2.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	9.9

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6A
Statistical analysis description:	
For serotype 6A the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	7.6

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 7F
Statistical analysis description:	
For serotype 7F the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	2.8

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19A
Statistical analysis description:	
For serotype 19A the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series

Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	3.5

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions

End point title	Percentage of Subjects Reporting Pre-Specified Local

End point description:

Local reactions (LRs) were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant(Sig) (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (Mod) (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine; (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary

End point timeframe:

During the 4-day period after each dose

Notes:

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

End point values	13vPnC Manufacturing Dose 1	13vPnC Pilot Dose 1	13vPnC Manufacturing Dose 2	13vPnC Pilot Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	134	134	132	133
Units: Percentage of subjects				
number (not applicable)				
Tenderness-Any (n=133,130,128,128,124,119,115,117)	18.8	20	20.3	17.2
Tenderness-Sig (n=131,129,128,128,124,119,112,114)	0.8	3.9	1.6	3.1
Swelling-Any (n=132,130,129,129,126,122,113,115)	25	20	30.2	27.1
Swelling-Mild (n=132,130,129,129,126,121,113,115)	22.7	17.7	29.5	25.6
Swelling-Mod (n=132,129,128,128,124,120,113,114)	6.1	7	8.6	8.6
Swelling-Severe(n=131,129,128,128,124,119,11	0	0	0	0
Redness-Any (n=132,131,129,131,125,123,115,116)	28.8	24.4	37.2	33.6
Redness-Mild (n=132,131,129,131,125,123,115,115)	28.8	22.9	36.4	33.6
Redness-Mod (n=131,129,128,128,124,119,113,114)	0	1.6	3.1	1.6

Redness-Severe(n=131,129,128,128,124,119,11	0	0	0	0

End point values	13vPnC Manufacturing Dose 3	13vPnC Pilot Dose 3	13vPnC Manufacturing Toddler Dose	13vPnC Pilot Toddler Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	132	133	131	131
Units: Percentage of subjects				
number (not applicable)				
Tenderness-Any (n=133,130,128,128,124,119,115,117)	15.3	12.6	24.3	29.1
Tenderness-Sig (n=131,129,128,128,124,119,112,114)	1.6	0	1.8	3.5
Swelling-Any (n=132,130,129,129,126,122,113,115)	29.4	30.3	22.1	26.1
Swelling-Mild (n=132,130,129,129,126,121,113,115)	27	25.6	22.1	25.2
Swelling-Mod (n=132,129,128,128,124,120,113,114)	8.9	13.3	8.8	8.8
Swelling-Severe(n=131,129,128,128,124,119,11	0	0	0	0
Redness-Any (n=132,131,129,131,125,123,115,116)	40	34.1	37.4	42.2
Redness-Mild (n=132,131,129,131,125,123,115,115)	38.4	33.3	33.9	36.5
Redness-Mod (n=131,129,128,128,124,119,113,114)	5.6	3.4	10.6	12.3
Redness-Severe(n=131,129,128,128,124,119,11	0	0	0	0.9

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events (Infant Series)[2]

End point description:

Systemic events (SEs) (fever greater than or equal to [>=] 38 degrees Celsius [C] but less than or equal to[=<] 39 C, fever more than [>]39 C but [=<] 40 C, fever > 40 C), decreased appetite, irritability, increased sleep, decreased sleep, use of medication (Meds) to prevent symptoms (sx), and use of medication to treat symptoms) were collected using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects (268) who received at least 1 dose of vaccine; (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary

End point timeframe:

During the 4-day period after each dose

Notes:

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

End point values	13vPnC Manufacturing Dose 1	13vPnC Pilot Dose 1	13vPnC Manufacturing Dose 2	13vPnC Pilot Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	134	134	132	133
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 C but =<39C (n=132,130,129,130,124,121)	18.2	19.2	16.3	20
Fever >39 C but =<40 C (n=131,129,128,128,124,119)	0.8	0.8	0.8	1.6
Fever >40 C (n=131,129,128,128,124,119)	0	0	0	0
Decreased appetite (n=133,129,129,128,125,121)	20.3	24	14.7	15.6
Irritability (n=134,131,130,131,127,123)	50	51.9	53.8	49.6
Increased sleep (n=132,129,128,129,124,121)	41.7	39.5	25	29.5
Decreased sleep (n=132,130,129,129,124,123)	27.3	32.3	24	20.9
Meds to treat sx (n=132,130,128,128,124,123)	12.9	17.7	13.3	14.1
Meds to prevent sx (n=132,130,128,129,124,121)	12.9	9.2	11.7	10.1

End point values	13vPnC Manufacturing Dose 3	13vPnC Pilot Dose 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	132	133		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 C but =<39C (n=132,130,129,130,124,121)	11.3	17.4		
Fever >39 C but =<40 C (n=131,129,128,128,124,119)	0	3.4		
Fever >40 C (n=131,129,128,128,124,119)	0	0		
Decreased appetite (n=133,129,129,128,125,121)	16.8	19		
Irritability (n=134,131,130,131,127,123)	41.7	37.4		
Increased sleep (n=132,129,128,129,124,121)	20.2	30.6		
Decreased sleep (n=132,130,129,129,124,123)	18.5	19.5		
Meds to treat sx (n=132,130,128,128,124,123)	8.9	14.6		
Meds to prevent sx (n=132,130,128,129,124,121)	10.5	8.3		

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects Reporting Pre-Specified Systemic Events (Toddler Series)[3]

End point description:

Systemic events (fever >= 38 C but =< 39 C, fever >39 C but =< 40 C, fever > 40 C), decreased appetite, irritability, increased sleep, decreased sleep, use of medication to prevent symptoms, and use of medication to treat symptoms) were collected using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine; (n) = number of subjects reporting yes for at least 1 day or no for all days.

End point type	Primary

End point timeframe:

During the 4-day period after toddler dose

Notes:

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

End point values	13vPnC Manufacturing Infant Series	13vPnC Pilot Infant Series		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	131	131		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 degrees C but =<39 degrees C(n=114,114)	14	13.2		
Fever >39 degrees C but =<40 degrees C (n=112,113)	0.9	0.9		
Fever >40 degrees C (n=112,113)	0	0		
Decreased appetite (n=115,117)	20.9	23.1		
Irritability (n=119,123)	40.3	44.7		
Increased sleep (n=114,119)	18.4	16.8		
Decreased sleep (n=116,117)	13.8	13.7		
Medication to treat symptoms (n=113,115)	17.7	17.4		
Medication to prevent symptoms (n=114,114)	12.3	12.3		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Antibody Concentration in 13vPnC Manufacturing Scale Group Relative to 13vPnC Pilot Scale Group After the 3-Dose Infant Series

End point title	Geometric Mean Antibody Concentration in 13vPnC Manufacturing Scale Group Relative to 13vPnC Pilot Scale Group After the 3-Dose Infant Series

End point description:

Antibody concentration/geometric mean concentration (GMC) as measured by enzyme-linked immunosorbent assay (ELISA) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F,

Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	1.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.65

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6B
Statistical analysis description: For serotype 6B the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.31

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 9V
Statistical analysis description: For serotype 9V the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.24

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 14

Statistical analysis description:	
For serotype 14 the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.22

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 18C
Statistical analysis description:	
For serotype 18C the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.3

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19F
Statistical analysis description:	
For serotype 19F the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.17

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 23F
Statistical analysis description: For serotype 23F the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.15

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 1
Statistical analysis description: For serotype 1 the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.37

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 3
Statistical analysis description: For serotype 3 the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.2

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 5
Statistical analysis description: For serotype 5 the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.16

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6A
Statistical analysis description: For serotype 6A the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.05

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 7F
Statistical analysis description: For serotype 7F the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series

Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.11

Statistical analysis title	13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19A
Statistical analysis description: For serotype 19A the GMC ratio was calculated.	
Comparison groups	13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.13

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were reported from signing of informed consent from (ICF) to 1 month after third dose in infant series & from toddler dose to 1 month after last study vaccination. SAEs were reported from the signing of the ICF to 1 month after last study vaccination

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included AEs collected in electronic diary (local,systemic reactions for 13vPnC; systematic assessment) and AEs collected on case report form at each visit (non systematic assessment). Subjects who received specified dose and had safety data available were evaluable for safety.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC Manufacturing Infant Series

Reporting group description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

Reporting group title	13vPnC Pilot Infant Series

Reporting group description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered withDTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

Reporting group title	13vPnC Manufacturing Post-Infant Series

Reporting group description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). Assessment done at 5 months of age, 1 month after infant series.

Reporting group title	13vPnC Pilot Post-Infant Series

Reporting group description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). Assessment done at 5 months of age, 1 month after infant series.

Reporting group title	13vPnC Manufacturing Toddler Series

Reporting group description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose).

Reporting group title	113vPnC Pilot Toddler Series

Reporting group description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose).

Serious adverse events	13vPnC Manufacturing Infant Series	13vPnC Pilot Infant Series	13vPnC Manufacturing Post-Infant Series
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 134 (2.99%)	2 / 134 (1.49%)	10 / 134 (7.46%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (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			
Diarrhoea			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	2 / 134 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (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			
Bronchospasm			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (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
Asthma			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	2 / 134 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Crying			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	2 / 134 (1.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	2 / 134 (1.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (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
Sepsis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			

subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	3 / 134 (2.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (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			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (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
Pharyngitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (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 primary atypical			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Pilot Post-Infant Series	13vPnC Manufacturing Toddler Series	113vPnC Pilot Toddler Series
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 134 (8.21%)	0 / 131 (0.00%)	1 / 131 (0.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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			
Conjunctivitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (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
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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			
Bronchitis			
subjects affected / exposed	2 / 134 (1.49%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 134 (2.24%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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
Sepsis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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	2 / 134 (1.49%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			

subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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
Enterocolitis infectious			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (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	4 / 134 (2.99%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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
Nasopharyngitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (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
Pharyngitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia primary atypical			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (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
Rotavirus infection			

subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (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 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (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

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

Non-serious adverse events	13vPnC Manufacturing Infant Series	13vPnC Pilot Infant Series	13vPnC Manufacturing Post-Infant Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	70 / 134 (52.24%)	68 / 134 (50.75%)	3 / 134 (2.24%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 134 (1.49%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	2	0	0

subjects affected / exposed[2]	1 / 131 (0.76%)	1 / 129 (0.78%)	0 / 134 (0.00%)
occurrences (all)	1	1	0
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	27 / 133 (20.30%)	31 / 129 (24.03%)	0 / 134 (0.00%)
occurrences (all)	27	31	0
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	67 / 134 (50.00%)	68 / 131 (51.91%)	0 / 134 (0.00%)
occurrences (all)	67	68	0
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	55 / 132 (41.67%)	51 / 129 (39.53%)	0 / 134 (0.00%)
occurrences (all)	55	51	0
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	36 / 132 (27.27%)	42 / 130 (32.31%)	0 / 134 (0.00%)
occurrences (all)	36	42	0
Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	21 / 129 (16.28%)	26 / 130 (20.00%)	0 / 134 (0.00%)
occurrences (all)	21	26	0
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[8]	1 / 128 (0.78%)	2 / 128 (1.56%)	0 / 134 (0.00%)
occurrences (all)	1	2	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[9]	19 / 129 (14.73%)	20 / 128 (15.63%)	0 / 134 (0.00%)
occurrences (all)	19	20	0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[10]	70 / 130 (53.85%)	65 / 131 (49.62%)	0 / 134 (0.00%)
occurrences (all)	70	65	0
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[11]	32 / 128 (25.00%)	38 / 129 (29.46%)	0 / 134 (0.00%)
occurrences (all)	32	38	0
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[12]	31 / 129 (24.03%)	27 / 129 (20.93%)	0 / 134 (0.00%)
occurrences (all)	31	27	0
Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[13]	14 / 124 (11.29%)	21 / 121 (17.36%)	0 / 134 (0.00%)
occurrences (all)	14	21	0
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 124 (0.00%)	4 / 119 (3.36%)	0 / 134 (0.00%)
occurrences (all)	0	4	0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	21 / 125 (16.80%)	23 / 121 (19.01%)	0 / 134 (0.00%)
occurrences (all)	21	23	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	53 / 127 (41.73%)	46 / 123 (37.40%)	0 / 134 (0.00%)
occurrences (all)	53	46	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	25 / 124 (20.16%)	37 / 121 (30.58%)	0 / 134 (0.00%)
occurrences (all)	25	37	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	23 / 124 (18.55%)	24 / 123 (19.51%)	0 / 134 (0.00%)
occurrences (all)	23	24	0
Immune system disorders			

Food allergy			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Posthitis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	2 / 134 (1.49%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	2	0	0
Asthma			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Psychomotor retardation			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Corneal abrasion			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			

Hip dysplasia			
subjects affected / exposed	1 / 134 (0.75%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	1	1	0
Atrial septal defect			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis congenital			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Hydrocele			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Plagiocephaly			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Hypotonia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 134 (1.49%)	2 / 134 (1.49%)	0 / 134 (0.00%)
occurrences (all)	2	2	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Lymphadenitis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Eye disorders			

Conjunctivitis			
subjects affected / exposed	5 / 134 (3.73%)	4 / 134 (2.99%)	0 / 134 (0.00%)
occurrences (all)	5	5	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Eyelid oedema			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 134 (2.99%)	3 / 134 (2.24%)	0 / 134 (0.00%)
occurrences (all)	5	3	0
Dyspepsia			
subjects affected / exposed	1 / 134 (0.75%)	4 / 134 (2.99%)	0 / 134 (0.00%)
occurrences (all)	1	4	0
Constipation			
subjects affected / exposed	1 / 134 (0.75%)	2 / 134 (1.49%)	0 / 134 (0.00%)
occurrences (all)	1	2	0
Abdominal pain			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Enlarged uvula			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Infantile colic			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Teething			

subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	1 / 134 (0.75%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 134 (1.49%)	2 / 134 (1.49%)	0 / 134 (0.00%)
occurrences (all)	3	2	0
Dermatitis atopic			
subjects affected / exposed	1 / 134 (0.75%)	2 / 134 (1.49%)	1 / 134 (0.75%)
occurrences (all)	1	2	1
Dermatitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	25 / 133 (18.80%)	26 / 130 (20.00%)	0 / 134 (0.00%)
occurrences (all)	25	26	0
Tenderness (significant): Infant series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[20]	1 / 131 (0.76%)	5 / 129 (3.88%)	0 / 134 (0.00%)
occurrences (all)	1	5	0
Induration (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	33 / 132 (25.00%)	26 / 130 (20.00%)	0 / 134 (0.00%)
occurrences (all)	33	26	0
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	30 / 132 (22.73%)	23 / 130 (17.69%)	0 / 134 (0.00%)
occurrences (all)	30	23	0
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
subjects affected / exposed[23]	8 / 132 (6.06%)	9 / 129 (6.98%)	0 / 134 (0.00%)
occurrences (all)	8	9	0
Erythema (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	38 / 132 (28.79%)	32 / 131 (24.43%)	0 / 134 (0.00%)
occurrences (all)	38	32	0
Erythema (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	38 / 132 (28.79%)	30 / 131 (22.90%)	0 / 134 (0.00%)
occurrences (all)	38	30	0
Erythema (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

subjects affected / exposed[26]	0 / 131 (0.00%)	2 / 129 (1.55%)	0 / 134 (0.00%)
occurrences (all)	0	2	0
Erythema (severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 131 (0.00%)	0 / 129 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	26 / 128 (20.31%)	22 / 128 (17.19%)	0 / 134 (0.00%)
occurrences (all)	26	22	0
Tenderness (significant): Infant series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	2 / 128 (1.56%)	4 / 128 (3.13%)	0 / 134 (0.00%)
occurrences (all)	2	4	0
Induration (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	39 / 129 (30.23%)	35 / 129 (27.13%)	0 / 134 (0.00%)
occurrences (all)	39	35	0
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	38 / 129 (29.46%)	33 / 129 (25.58%)	0 / 134 (0.00%)
occurrences (all)	38	33	0
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[32]	11 / 128 (8.59%)	11 / 128 (8.59%)	0 / 134 (0.00%)
occurrences (all)	11	11	0
Erythema (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[33]	48 / 129 (37.21%)	44 / 131 (33.59%)	0 / 134 (0.00%)
occurrences (all)	48	44	0
Erythema (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[34]	47 / 129 (36.43%)	44 / 131 (33.59%)	0 / 134 (0.00%)
occurrences (all)	47	44	0
Erythema (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[35]	4 / 128 (3.13%)	2 / 128 (1.56%)	0 / 134 (0.00%)
occurrences (all)	4	2	0
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[36]	19 / 124 (15.32%)	15 / 119 (12.61%)	0 / 134 (0.00%)
occurrences (all)	19	15	0
Tenderness(significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[37]	2 / 124 (1.61%)	0 / 119 (0.00%)	0 / 134 (0.00%)
occurrences (all)	2	0	0
Induration (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	37 / 126 (29.37%)	37 / 122 (30.33%)	0 / 134 (0.00%)
occurrences (all)	37	37	0
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	34 / 126 (26.98%)	31 / 121 (25.62%)	0 / 134 (0.00%)
occurrences (all)	34	31	0
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	11 / 124 (8.87%)	16 / 120 (13.33%)	0 / 134 (0.00%)
occurrences (all)	11	16	0
Erythema (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]			0 / 134 (0.00%)

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[43]	7 / 124 (5.65%)	4 / 119 (3.36%)	0 / 134 (0.00%)
occurrences (all)	7	4	0
Musculoskeletal and connective tissue disorders			
Rickets			
subjects affected / exposed	1 / 134 (0.75%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	1	2	0
Posture abnormal			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Rhinitis			
subjects affected / exposed	12 / 134 (8.96%)	10 / 134 (7.46%)	0 / 134 (0.00%)
occurrences (all)	12	11	0
Pharyngitis			
subjects affected / exposed	9 / 134 (6.72%)	10 / 134 (7.46%)	0 / 134 (0.00%)
occurrences (all)	10	10	0
Upper respiratory tract infection			
subjects affected / exposed	8 / 134 (5.97%)	11 / 134 (8.21%)	0 / 134 (0.00%)
occurrences (all)	8	12	0
Nasopharyngitis			
subjects affected / exposed	8 / 134 (5.97%)	9 / 134 (6.72%)	0 / 134 (0.00%)
occurrences (all)	8	10	0
Bronchitis			
subjects affected / exposed	5 / 134 (3.73%)	7 / 134 (5.22%)	0 / 134 (0.00%)
occurrences (all)	5	8	0
Candidiasis			
subjects affected / exposed	2 / 134 (1.49%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	2	1	0
Ear infection			
subjects affected / exposed	2 / 134 (1.49%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	2	1	0
Exanthema subitum			

subjects affected / exposed	2 / 134 (1.49%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	2	1	0
Viral infection			
subjects affected / exposed	2 / 134 (1.49%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	2	1	0
Bronchopneumonia			
subjects affected / exposed	1 / 134 (0.75%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal infection			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	2	0	0
Oral candidiasis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 134 (0.75%)	0 / 134 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 134 (0.00%)	0 / 134 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	13vPnC Pilot Post-Infant Series	13vPnC Manufacturing Toddler Series	113vPnC Pilot Toddler Series
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 134 (5.22%)	48 / 131 (36.64%)	55 / 131 (41.98%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 134 (0.00%)	2 / 131 (1.53%)	0 / 131 (0.00%)
occurrences (all)	0	2	0
Irritability			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C: Infant series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 134 (0.00%)	16 / 114 (14.04%)	15 / 114 (13.16%)
occurrences (all)	0	16	15
Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 134 (0.00%)	1 / 112 (0.89%)	1 / 113 (0.88%)
occurrences (all)	0	1	1
Decreased appetite: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 134 (0.00%)	24 / 115 (20.87%)	27 / 117 (23.08%)
occurrences (all)	0	24	27
Irritability: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 134 (0.00%)	48 / 119 (40.34%)	55 / 123 (44.72%)
occurrences (all)	0	48	55
Increased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 134 (0.00%)	21 / 114 (18.42%)	20 / 119 (16.81%)
occurrences (all)	0	21	20
Decreased sleep: Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 134 (0.00%)	16 / 116 (13.79%)	16 / 117 (13.68%)
occurrences (all)	0	16	16
Fever ≥38°C but ≤39°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is		

	same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Fever ≥38°C but ≤39°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Fever >39°C but ≤40°C: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Decreased appetite: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[15]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Irritability: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Increased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Decreased sleep: Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	1	0	0
Milk allergy			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Posthitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			

subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Crying			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Psychomotor retardation			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Corneal abrasion			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Hip dysplasia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Atrial septal defect			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis congenital			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Hydrocele			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Plagiocephaly			

subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hypertonia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	1	0	0
Poor quality sleep			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 134 (1.49%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	4	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	0 / 131 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 134 (0.00%)	3 / 131 (2.29%)	1 / 131 (0.76%)
occurrences (all)	0	3	1
Dyspepsia			

subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Enlarged uvula			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Infrequent bowel movements			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 134 (0.75%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	1 / 131 (0.76%)
occurrences (all)	0	1	1

Dermatitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	2 / 134 (1.49%)	1 / 131 (0.76%)	0 / 131 (0.00%)
occurrences (all)	2	1	0
Tenderness (any): Infant series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 134 (0.00%)	28 / 115 (24.35%)	34 / 117 (29.06%)
occurrences (all)	0	28	34
Tenderness (significant): Infant series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 134 (0.00%)	2 / 112 (1.79%)	4 / 114 (3.51%)
occurrences (all)	0	2	4
Induration (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 134 (0.00%)	25 / 113 (22.12%)	30 / 115 (26.09%)
occurrences (all)	0	25	30
Induration (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 134 (0.00%)	25 / 113 (22.12%)	29 / 115 (25.22%)
occurrences (all)	0	25	29
Induration (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one		

	occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
subjects affected / exposed[23]	0 / 134 (0.00%)	10 / 113 (8.85%)	10 / 114 (8.77%)
occurrences (all)	0	10	10
Erythema (any): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 134 (0.00%)	43 / 115 (37.39%)	49 / 116 (42.24%)
occurrences (all)	0	43	49
Erythema (mild): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 134 (0.00%)	39 / 115 (33.91%)	42 / 115 (36.52%)
occurrences (all)	0	39	42
Erythema (moderate): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
subjects affected / exposed[26]	0 / 134 (0.00%)	12 / 113 (10.62%)	14 / 114 (12.28%)
occurrences (all)	0	12	14
Erythema (severe): Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 134 (0.00%)	0 / 112 (0.00%)	1 / 113 (0.88%)

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Induration (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Induration (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Induration (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Erythema (any): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Erythema (mild): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[34]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Erythema (moderate): Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Tenderness (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Tenderness(significant): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Induration (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Induration (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Induration (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Erythema (any): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Erythema (mild): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Erythema (moderate): Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Rickets			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Posture abnormal			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Rhinitis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	2 / 131 (1.53%)
occurrences (all)	0	1	2
Pharyngitis			

subjects affected / exposed	0 / 134 (0.00%)	5 / 131 (3.82%)	5 / 131 (3.82%)
occurrences (all)	0	5	5
Upper respiratory tract infection			
subjects affected / exposed	0 / 134 (0.00%)	2 / 131 (1.53%)	1 / 131 (0.76%)
occurrences (all)	0	2	2
Nasopharyngitis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	2 / 131 (1.53%)
occurrences (all)	0	1	2
Bronchitis			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	2 / 131 (1.53%)
occurrences (all)	0	1	2
Candidiasis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	3 / 131 (2.29%)
occurrences (all)	0	1	3
Bronchopneumonia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			

subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 134 (0.00%)	2 / 131 (1.53%)	2 / 131 (1.53%)
occurrences (all)	0	2	2
Laryngitis			
subjects affected / exposed	0 / 134 (0.00%)	2 / 131 (1.53%)	0 / 131 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	1 / 131 (0.76%)
occurrences (all)	0	1	1
Otitis media acute			
subjects affected / exposed	0 / 134 (0.00%)	0 / 131 (0.00%)	1 / 131 (0.76%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 134 (0.00%)	1 / 131 (0.76%)	0 / 131 (0.00%)
occurrences (all)	0	1	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.
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[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.
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[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.
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[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.
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[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.
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[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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[25] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:

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

exposed for the reporting group. These numbers are expected to be equal.

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

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

Justification:
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported