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

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

Summary

EudraCT number	2008-004766-40
Trial protocol	Outside EU/EEA
Global end of trial date	20 November 2009

Results information

Result version number	v2 (current)
This version publication date	28 July 2016
First version publication date	01 August 2015
Version creation reason	• Correction of full data set reporting periods and duplicate AEs in their data

Trial information

Trial identification

Sponsor protocol code	6096A1-3004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00688870
WHO universal trial number (UTN)	-
Other trial identifiers	Protocol ID: B1851005

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 May 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 November 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the pneumococcal immune responses induced by 13 valent pneumococcal conjugate vaccine (13vPnC) relative to the pneumococcal immune responses induced by 7 valent pneumococcal conjugate vaccine (7vPnC) when measured 1 month 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	05 June 2008
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	Taiwan: 168
Worldwide total number of subjects	168
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	168
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 Taiwan from June 2008 to Nov 2009.

Pre-assignment

Screening details:

A total of 169 subjects were screened, 168 subjects were randomly assigned in a 1:1 ratio to either the 13vPnC group (n=84) or the 7vPnC group (n=84).

Period 1

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

Arms

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

Arm description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: diphtheria, tetanus, and acellular pertussis (DTaP); inactivated poliovirus (IPV); and Haemophilus influenzae type b (Hib). At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and hepatitis B virus (HBV) vaccine.

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

Dosage and administration details:

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

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

Dosage and administration details:

Subjects received a single intramuscular dose of DTaP-IPV-Hib at 2 and 4 months of age.

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

Dosage and administration details:

Subjects received a single intramuscular dose of DTaP-IPV-Hib-HBV at 6 months of age.

Arm title	Infant Series 7vPnC

Arm description:

Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age

(infant series). At 2 and 4 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 7vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

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

Dosage and administration details:

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

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

Dosage and administration details:

Subjects received a single intramuscular dose of DTaP-IPV-Hib at 2 and 4 months of age.

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

Dosage and administration details:

Subjects received a single intramuscular dose of DTaP-IPV-Hib-HBV at 6 months of age.

Number of subjects in period 1	Infant Series 13vPnC	Infant Series 7vPnC
Started	84	84
Vaccinated Dose 1	83	84
Vaccinated Dose 2	80	84
Vaccinated Dose 3	80	84
Completed	80	84
Not completed	4	0
Parent or legal guardian request	4	-

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	After Infant Series 13vPnC

Arm description:

Included subjects who received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	After Infant Series 7vPnC

Arm description:

Included subjects who received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	After Infant Series 13vPnC	After Infant Series 7vPnC
Started	80	84
Completed	80	84

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

Arms	
Are arms mutually exclusive?	Yes
Arm title	Toddler Series 13vPnC

Arm description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Arm type	Experimental

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of 13vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Arm title	Toddler Series 7vPnC

Arm description:

Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 15 months of age (toddler dose).

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

Dosage and administration details:

Subjects received 1 single 0.5 mL dose of 7vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Number of subjects in period 3	Toddler Series 13vPnC	Toddler Series 7vPnC
Started	80	84
Completed	80	84

Baseline characteristics

Reporting groups	
Reporting group title	Infant Series 13vPnC
Reporting group description:	
Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: diphtheria, tetanus, and acellular pertussis (DTaP); inactivated poliovirus (IPV); and Haemophilus influenzae type b (Hib). At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and hepatitis B virus (HBV) vaccine.	
Reporting group title	Infant Series 7vPnC
Reporting group description:	
Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 7vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.	

Reporting group values	Infant Series 13vPnC	Infant Series 7vPnC	Total
Number of subjects	84	84	168
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	2.2	2.3	
standard deviation	± 0.3	± 0.3	-
Gender categorical Units: Subjects			
Female	40	47	87
Male	44	37	81
Region of Enrollment Units: Subjects			
Taiwan	84	84	168

End points

End points reporting groups

Reporting group title	Infant Series 13vPnC

Reporting group description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: diphtheria, tetanus, and acellular pertussis (DTaP); inactivated poliovirus (IPV); and Haemophilus influenzae type b (Hib). At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and hepatitis B virus (HBV) vaccine.

Reporting group title	Infant Series 7vPnC

Reporting group description:

Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 7vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Reporting group title	After Infant Series 13vPnC

Reporting group description:

Included subjects who received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Reporting group title	After Infant Series 7vPnC

Reporting group description:

Included subjects who received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Reporting group title	Toddler Series 13vPnC

Reporting group description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Reporting group title	Toddler Series 7vPnC

Reporting group description:

Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Subject analysis set title	Infant Series 13vPnc Dose 1
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 2 months of age (infant series). At 2 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine DTaP; IPV; and Hib.

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

Subject analysis set description:

Subjects received 1 single dose of 7vPnC , administered intramuscularly, at 2 months of age (infant series). At 2 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine DTaP; IPV; and Hib.

Subject analysis set title	Infant Series 13vPnc Dose 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received 1 single dose of 13vPnc, administered intramuscularly, at 4 months of age (infant series).At 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine DTaP; IPV; and Hib.

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

Subject analysis set description:

Subjects received 1 single dose of 7vPnc, administered intramuscularly, at 4 months of age (infant series). At 4 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine DTaP; IPV; and Hib.

Subject analysis set title	Infant Series 13vPnc Dose 3
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received 1 single dose of 13vPnc, administered intramuscularly, at 6 months of age (infant series). At 6 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Subject analysis set title	Infant Series 7vPnC Dose 3
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects received 1 single dose of 7vPnc, administered intramuscularly, at 6 months of age (infant series). At 6 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine DTaP; IPV; and Hib. At 6 months of age during the infant series, 7vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Primary: Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to 0.35 Micrograms

End point title	Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to 0.35 Micrograms

End point description:

Percentage of subjects achieving a predefined antibody level of greater than or equal to (>=) 0.35 mcg/mL along with the corresponding exact 95 percentage (%) confidence interval (CI) for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented.
Evaluable immunogenicity population: had treatments as randomized at all 3 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay
result for the proposed analysis, and no major protocol violations.

End point type	Primary

End point timeframe:

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

End point values	Infant Series 13vPnC	Infant Series 7vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	83		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4	98.8 (93.2 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 6B	100 (95.5 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 9V	98.8 (93.2 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 14	100 (95.5 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 18C	100 (95.5 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 19F	98.8 (93.2 to 100)	100 (95.7 to 100)		

Common Serotypes - Serotype 23F	95 (87.7 to 98.6)	100 (95.7 to 100)		
Additional Serotypes - Serotype 1	98.8 (93.2 to 100)	2.4 (0.3 to 8.4)		
Additional Serotypes - Serotype 3	97.5 (91.3 to 99.7)	2.4 (0.3 to 8.4)		
Additional Serotypes - Serotype 5	98.8 (93.2 to 100)	61.5 (49.8 to 72.3)		
Additional Serotypes - Serotype 6A	100 (95.5 to 100)	77.1 (66.6 to 85.6)		
Additional Serotypes - Serotype 7F	100 (95.5 to 100)	2.4 (0.3 to 8.4)		
Additional Serotypes - Serotype 19A	100 (95.5 to 100)	100 (95.6 to 100)		

Statistical analyses

Statistical analysis title	Common Serotypes - Serotype 4
Comparison groups	Infant Series 7vPnC v Infant Series 13vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[1]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	3.3

Notes:

[1] - The statistical analyses was descriptive.

Statistical analysis title	Common Serotypes - Serotype 6B
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[2]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.3

Notes:

[2] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 9V

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[3]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	3.3

Notes:

[3] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 14
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[4]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.3

Notes:

[4] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 18C
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[5]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.3

Notes:

[5] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 19F
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[6]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	3.3

Notes:

[6] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 23F
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[7]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.3
upper limit	-0.3

Notes:

[7] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 1
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[8]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	96.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	89.4
upper limit	99.2

Notes:

[8] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 3
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[9]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	95.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	87.7
upper limit	98.6

Notes:

[9] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 5
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[10]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	37.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.2
upper limit	48.9

Notes:

[10] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 6A
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[11]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	22.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.4
upper limit	33.4

Notes:

[11] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 7F
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[12]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	97.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	91.6
upper limit	99.7

Notes:

[12] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 19A
Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[13]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.5

Notes:

[13] - The statistical analyses was descriptive.

Secondary: Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to 0.35 Mcg/mL, 1 Month After the Toddler Dose

End point title	Percentage of Subjects Achieving a Predefined Antibody Level of Greater Than or Equal to 0.35 Mcg/mL, 1 Month After the Toddler Dose

End point description:

Percentage of subjects achieving a predefined antibody level of >=0.35 mcg/mL along with the corresponding exact 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity population: had treatments as randomized at all 4 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after toddler dose (16 months of age)

End point values	Toddler Series 13vPnC	Toddler Series 7vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	84		
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4	98.7 (93.1 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 6B	100 (95.4 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 9V	98.7 (93.1 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 14	100 (95.4 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 18C	100 (95.4 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 19F	98.7 (93.1 to 100)	100 (95.7 to 100)		
Common Serotypes - Serotype 23F	100 (95.4 to 100)	100 (95.7 to 100)		
Additional Serotypes - Serotype 1	100 (95.4 to 100)	5 (1.4 to 12.3)		
Additional Serotypes - Serotype 3	96.2 (89.3 to 99.2)	13.8 (7.1 to 23.3)		
Additional Serotypes - Serotype 5	100 (95.4 to 100)	90.4 (81.9 to 95.7)		
Additional Serotypes - Serotype 6A	100 (95.4 to 100)	100 (95.7 to 100)		
Additional Serotypes - Serotype 7F	100 (95.4 to 100)	6.3 (2.1 to 14)		
Additional Serotypes - Serotype 19A	100 (95.4 to 100)	98.8 (93.5 to 100)		

Statistical analyses

Statistical analysis title	Common serotypes - serotype 4
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[14]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	3.1

Notes:

[14] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 6B
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[15]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.4

Notes:

[15] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 9V
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[16]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	3.1

Notes:

[16] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 14
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[17]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.4

Notes:

[17] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 18C
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[18]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.4

Notes:

[18] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 19F
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[19]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	3.1

Notes:

[19] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 23F
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[20]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.4

Notes:

[20] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 1
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[21]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	95
Confidence interval	
level	95 %
sides	2-sided
lower limit	87.7
upper limit	98.6

Notes:

[21] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 3
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[22]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	82.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	72
upper limit	90.1

Notes:

[22] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 5
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[23]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	9.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.8
upper limit	18.1

Notes:

[23] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 6A
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[24]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	4.4

Notes:

[24] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 7F
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[25]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	93.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	86
upper limit	97.9

Notes:

[25] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 19A
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[26]
Method	Chan and Zhang
Parameter estimate	Difference
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	6.5

Notes:

[26] - The statistical analyses was descriptive.

Other pre-specified: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 1 Month After the Infant Series

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 1 Month

	After the Infant Series

End point description:

Antibody GMC as measured in mcg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity population: had treatments as randomized at all 3 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations.

End point type	Other pre-specified

End point timeframe:

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

End point values	Infant Series 13vPnC	Infant Series 7vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	83		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4	2.89 (2.45 to 3.42)	4.64 (4 to 5.37)		
Common serotypes - serotype 6B	4.37 (3.58 to 5.33)	4.82 (4.09 to 5.67)		
Common serotypes - serotype 9V	1.97 (1.7 to 2.27)	2.92 (2.55 to 3.34)		
Common serotypes - serotype 14	9.76 (8.34 to 11.43)	11.59 (9.79 to 13.71)		
Common serotypes - serotype 18C	2.39 (2.04 to 2.82)	3.07 (2.64 to 3.56)		
Common serotypes - serotype 19F	3.6 (3 to 4.32)	4.77 (4.17 to 5.47)		
Common serotypes - serotype 23F	1.93 (1.56 to 2.37)	3.25 (2.78 to 3.8)		
Additional serotypes - serotype 1	4.14 (3.45 to 4.96)	0.02 (0.02 to 0.02)		
Additional serotypes - serotype 3	1.2 (1 to 1.45)	0.05 (0.04 to 0.06)		
Additional serotypes - serotype 5	2.47 (2.09 to 2.92)	0.43 (0.35 to 0.53)		
Additional serotypes - serotype 6A	4.57 (3.92 to 5.34)	0.79 (0.63 to 0.99)		
Additional serotypes - serotype 7F	3.67 (3.14 to 4.29)	0.04 (0.03 to 0.05)		
Additional serotypes - serotype 19A	3.69 (3.2 to 4.24)	2.46 (2.13 to 2.84)		

Statistical analyses

Statistical analysis title	Common serotypes - serotype 4

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[27]
Parameter estimate	ratio of GMCs
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.78

Notes:

[27] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 6B

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[28]
Parameter estimate	ratio of GMCs
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.17

Notes:

[28] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 9V

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[29]
Parameter estimate	ratio of GMCs
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.82

Notes:

[29] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 14

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[30]
Parameter estimate	ratio of GMCs
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.06

Notes:

[30] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 18C

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[31]
Parameter estimate	ratio of GMCs
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.97

Notes:

[31] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 19F

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[32]
Parameter estimate	ratio of GMCs
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.94

Notes:

[32] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 23F

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[33]
Parameter estimate	ratio of GMCs
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	0.77

Notes:

[33] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 1

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[34]
Parameter estimate	ratio of GMCs
Point estimate	202.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	157.04
upper limit	261.32

Notes:

[34] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 3

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[35]
Parameter estimate	ratio of GMCs
Point estimate	24.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	18.46
upper limit	31.49

Notes:

[35] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 5

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[36]
Parameter estimate	ratio of GMCs
Point estimate	5.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.37
upper limit	7.41

Notes:

[36] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 6A

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[37]
Parameter estimate	ratio of GMCs
Point estimate	5.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.42
upper limit	7.67

Notes:

[37] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 7F

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[38]
Parameter estimate	ratio of GMCs
Point estimate	96.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	75.6
upper limit	122.17

Notes:

[38] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 19A

Statistical analysis description:

Confidence intervals for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC-7vPnC reference).

Comparison groups	Infant Series 13vPnC v Infant Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[39]
Parameter estimate	ratio of GMCs
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	1.83

Notes:

[39] - The statistical analyses was descriptive.

Other pre-specified: GMC for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 1 Month After the Toddler Dose

End point title	GMC for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody, 1 Month After the Toddler Dose

End point description:

Antibody GMC as measured in mcg/mL for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity population: had treatments as randomized at all 3 doses, blood drawn within specified timeframes, had at least 1 valid and determinate assay result for the proposed analysis, and no major protocol violations.

End point type	Other pre-specified

End point timeframe:

1 month after the toddler dose (16 months of age)

End point values	Toddler Series 13vPnC	Toddler Series 7vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	84		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4	4.06 (3.34 to 4.93)	6.34 (5.26 to 7.65)		
Common serotypes - serotype 6B	13.62 (11.08 to 16.73)	13.28 (10.87 to 16.21)		
Common serotypes - serotype 9V	3.18 (2.66 to 3.8)	3.88 (3.27 to 4.6)		
Common serotypes - serotype 14	8.17 (6.53 to 10.22)	12.04 (9.9 to 14.63)		
Common serotypes - serotype 18C	3.67 (3 to 4.49)	4.87 (4.01 to 5.9)		
Common serotypes - serotype 19F	8.07 (6.58 to 9.9)	7.41 (6.16 to 8.92)		
Common serotypes - serotype 23F	5.51 (4.46 to 6.81)	7.97 (6.55 to 9.68)		
Additional serotypes - serotype 1	7.62 (6.3 to 9.21)	0.03 (0.02 to 0.03)		
Additional serotypes - serotype 3	1.29 (1.09 to 1.53)	0.12 (0.09 to 0.16)		
Additional serotypes - serotype 5	4.57 (3.87 to 5.39)	0.95 (0.8 to 1.13)		
Additional serotypes - serotype 6A	11.55 (9.66 to 13.81)	3.79 (3.01 to 4.76)		
Additional serotypes - serotype 7F	5.91 (4.95 to 7.06)	0.06 (0.04 to 0.07)		
Additional serotypes - serotype 19A	8.82 (7.45 to 10.43)	1.98 (1.69 to 2.32)		

Statistical analyses

Statistical analysis title	Common serotypes - serotype 4
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[40]
Parameter estimate	ratio of GMC
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.84

Notes:

[40] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 6B
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[41]
Parameter estimate	ratio of GMC
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.36

Notes:

[41] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 9V
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[42]
Parameter estimate	ratio of GMC
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.05

Notes:

[42] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 14
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[43]
Parameter estimate	ratio of GMC
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.91

Notes:

[43] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 18C
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[44]
Parameter estimate	ratio of GMC
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.99

Notes:

[44] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 19F
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[45]
Parameter estimate	ratio of GMC
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.43

Notes:

[45] - The statistical analyses was descriptive.

Statistical analysis title	Common serotypes - serotype 23F
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[46]
Parameter estimate	ratio of GMC
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.92

Notes:

[46] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 1
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[47]
Parameter estimate	ratio of GMC
Point estimate	303.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	213.63
upper limit	431.83

Notes:

[47] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 3
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[48]
Parameter estimate	ratio of GMC
Point estimate	10.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.77
upper limit	14.62

Notes:

[48] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 5
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[49]
Parameter estimate	ratio of GMC
Point estimate	4.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.78
upper limit	6.08

Notes:

[49] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 6A
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[50]
Parameter estimate	ratio of GMC
Point estimate	3.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.28
upper limit	4.08

Notes:

[50] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 7F
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[51]
Parameter estimate	ratio of GMC
Point estimate	105
Confidence interval	
level	95 %
sides	2-sided
lower limit	75.6
upper limit	145.84

Notes:

[51] - The statistical analyses was descriptive.

Statistical analysis title	Additional serotypes - serotype 19A
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	other[52]
Parameter estimate	ratio of GMC
Point estimate	4.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.54
upper limit	5.6

Notes:

[52] - The statistical analyses was descriptive.

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 1 (2 Months of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 1 (2 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling and redness present); Mild (0.5 to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm).

Subjects may be represented in more than 1 category. Safety population: all subjects who received dose 1 of the infant series vaccination (2 months of age). (n)= number of subjects reporting yes for at least 1 day or no for all days.

End point type	Other pre-specified

End point timeframe:

Within 4 days after Dose 1 of the infant series (2 Months of Age)

End point values	Infant Series 13vPnc Dose 1	Infant Series 7vPnC Dose 1		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	83	84		
Units: percentage of subjects				
number (not applicable)				
Tenderness - Any	31.3	34.2		
Tenderness - Significant	5.3	9.3		
Swelling - Any	25.6	11.8		
Swelling - Mild	24.4	11.8		
Swelling - Moderate (n=74,74)	1.4	0		
Swelling - Severe (n=74,74)	0	0		
Redness - Any	29.9	28.9		
Redness - Mild	26	26.3		
Redness - Moderate (n=74,74)	8.1	2.7		
Redness - Severe (n=74,74)	0	0		

Statistical analyses

Statistical analysis title	Tenderness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[53]
P-value	= 0.735
Method	Fisher exact

Notes:

[53] - The statistical analyses was descriptive.

Statistical analysis title	Tenderness - Significant

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[54]
P-value	= 0.533
Method	Fisher exact

Notes:

[54] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[55]
P-value	= 0.039
Method	Fisher exact

Notes:

[55] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[56]
P-value	= 0.059
Method	Fisher exact

Notes:

[56] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[57]
P-value	> 0.99
Method	Fisher exact

Notes:

[57] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Severe
Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[58]
P-value	= 99999 [59]
Method	Fisher exact

Notes:

[58] - The statistical analyses was descriptive.

[59] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe swelling in either treatment group, p-value could not be estimated.

Statistical analysis title	Redness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[60]
P-value	> 0.99
Method	Fisher exact

Notes:

[60] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[61]
P-value	> 0.99
Method	Fisher exact

Notes:

[61] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[62]
P-value	= 0.275
Method	Fisher exact

Notes:

[62] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Severe
Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[63]
P-value	= 99999 [64]
Method	Fisher exact

Notes:

[63] - The statistical analyses was descriptive.

[64] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe redness in either treatment group, p-value could not be estimated.

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 2 (4 Months of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 2 (4 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling and redness present); Mild (0.5 to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received the first 2 doses of the infant series vaccination (4 months of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group
respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 Days after Dose 2 of the infant series (4 months of age)

End point values	Infant Series 13vPnc Dose 2	Infant Series 7vPnC Dose 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	80	84		
Units: percentage of subjects				
number (not applicable)				
Tenderness - Any	23.6	22.4		
Tenderness - Significant (n=69,71)	2.9	1.4		
Swelling - Any (n=70,72)	12.9	15.3		
Swelling - Mild (n=70,72)	12.9	15.3		
Swelling - Moderate (n=69,71)	0	0		
Swelling - Severe (n=69,71)	0	0		
Redness - Any (n=70,74)	17.1	20.3		
Redness - Mild (n=70,74)	17.1	17.6		
Redness - Moderate (n=69,71)	0	2.8		
Redness - Severe (n=69,71)	0	0		

Statistical analyses

Statistical analysis title	Tenderness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[65]
P-value	> 0.99
Method	Fisher exact

Notes:

[65] - The statistical analyses was descriptive.

Statistical analysis title	Tenderness - Significant

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[66]
P-value	= 0.617
Method	Fisher exact

Notes:

[66] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[67]
P-value	= 0.81
Method	Fisher exact

Notes:

[67] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[68]
P-value	= 0.81
Method	Fisher exact

Notes:

[68] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Moderate
Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[69]
P-value	= 99999 [70]
Method	Fisher exact

Notes:

[69] - The statistical analyses was descriptive.

[70] - Here, 99999 in the p-
value signifies "Not estimable". Since there were no subject with moderate swelling in either treatment g
roup, p-value could not be estimated.

Statistical analysis title	Swelling - Severe
Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[71]
P-value	= 99999 [72]
Method	Fisher exact

Notes:

[71] - The statistical analyses was descriptive.

[72] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe swelling in either treatment group, p-value could not be estimated.

Statistical analysis title	Redness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[73]
P-value	= 0.674
Method	Fisher exact

Notes:

[73] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[74]
P-value	> 0.99
Method	Fisher exact

Notes:

[74] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[75]
P-value	= 0.497
Method	Fisher exact

Notes:

[75] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Severe
Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[76]
P-value	= 99999 [77]
Method	Fisher exact

Notes:

[76] - The statistical analyses was descriptive.

[77] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe redness in either treatment group, p-value could not be estimated.

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 3 (6 Months of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Infant Series Dose 3 (6 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling and redness present); Mild (0.5 to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received all 3 doses of the infant series vaccination (6 months of age). n=number of subjects reporting yes for at least 1 day or no for all days for each treatment group
respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after Dose 3 of the infant series (6 months of age)

End point values	Infant Series 13vPnc Dose 3	Infant Series 7vPnC Dose 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	80	84		
Units: percentage of subjects				
number (not applicable)				
Tenderness - Any (n=67,67)	19.4	17.9		
Tenderness - Significant (n=65,65)	0	1.5		
Swelling - Any (n=65,65)	16.9	4.6		
Swelling - Mild (n=65,65)	15.4	4.6		
Swelling - Moderate (n=65,64)	3.1	0		
Swelling - Severe (n=65,64)	0	0		
Redness - Any (n=67,65)	20.9	13.8		
Redness - Mild (n=66,65)	18.2	13.8		
Redness - Moderate (n=66,64)	4.5	0		

Redness - Severe (n=65,64)	0	0		

Statistical analyses

Statistical analysis title	Tenderness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[78]
P-value	> 0.99
Method	Fisher exact

Notes:

[78] - The statistical analyses was descriptive.

Statistical analysis title	Tenderness - Significant

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[79]
P-value	> 0.99
Method	Fisher exact

Notes:

[79] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[80]
P-value	= 0.044
Method	Fisher exact

Notes:

[80] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[81]
P-value	= 0.076
Method	Fisher exact

Notes:

[81] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[82]
P-value	= 0.496
Method	Fisher exact

Notes:

[82] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Severe
Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[83]
P-value	= 99999 [84]
Method	Fisher exact

Notes:

[83] - The statistical analyses was descriptive.

[84] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe swelling in either treatment group, p-value could not be estimated.

Statistical analysis title	Redness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[85]
P-value	= 0.361
Method	Fisher exact

Notes:

[85] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[86]
P-value	= 0.635
Method	Fisher exact

Notes:

[86] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[87]
P-value	= 0.244
Method	Fisher exact

Notes:

[87] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Severe
Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[88]
P-value	= 99999 [89]
Method	Fisher exact

Notes:

[88] - The statistical analyses was descriptive.

[89] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe redness in either treatment group, p-value could not be estimated.

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions: Toddler Dose (15 Months of Age)

End point title	Percentage of Subjects With Pre-specified Local Reactions: Toddler Dose (15 Months of Age)

End point description:

Local reactions were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant (present and interfered with limb movement). Swelling and redness were scaled as Any (swelling and redness present); Mild (0.5 to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may be represented in more than 1 category. Safety population: all subjects who received the toddler dose (15 months of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after the toddler dose (15 months of age)

End point values	Toddler Series 13vPnC	Toddler Series 7vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	84		
Units: percentage of subjects				
number (not applicable)				
Tenderness - Any (n=64,75)	10.9	22.7		
Tenderness - Significant (n=63,69)	0	0		
Swelling - Any (n=63,70)	7.9	5.7		
Swelling - Mild (n=63,70)	6.3	5.7		
Swelling - Moderate (n=63,69)	1.6	0		
Swelling - Severe (n=63,69)	0	0		
Redness - Any (n=65,70)	15.4	12.9		
Redness - Mild (n=65,70)	13.8	12.9		
Redness - Moderate (n=63,69)	1.6	0		
Redness - Severe (n=63,69)	0	0		

Statistical analyses

Statistical analysis title	Tenderness - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 7vPnC v Toddler Series 13vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[90]
P-value	= 0.076
Method	Fisher exact

Notes:

[90] - The statistical analyses was descriptive.

Statistical analysis title	Tenderness - Significant
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[91]
P-value	= 99999 [92]
Method	Fisher exact

Notes:

[91] - The statistical analyses was descriptive.

[92] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with significant tenderness in either treatment group, p-value could not be estimated.

Statistical analysis title	Swelling - Any

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[93]
P-value	= 0.735
Method	Fisher exact

Notes:

[93] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[94]
P-value	> 0.99
Method	Fisher exact

Notes:

[94] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[95]
P-value	= 0.477
Method	Fisher exact

Notes:

[95] - The statistical analyses was descriptive.

Statistical analysis title	Swelling - Severe
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[96]
P-value	= 99999 [97]
Method	Fisher exact

Notes:

[96] - The statistical analyses was descriptive.

[97] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe swelling in either treatment group, p-value could not be estimated.

Statistical analysis title	Redness - Any
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[98]
P-value	= 0.805
Method	Fisher exact

Notes:

[98] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Mild

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[99]
P-value	> 0.99
Method	Fisher exact

Notes:

[99] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Moderate

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[100]
P-value	= 0.477
Method	Fisher exact

Notes:

[100] - The statistical analyses was descriptive.

Statistical analysis title	Redness - Severe
Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[101]
P-value	= 99999 [102]
Method	Fisher exact

Notes:

[101] - The statistical analyses was descriptive.

[102] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with severe redness in either treatment group, p-value could not be estimated.

Other pre-specified: Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 1 (2 Months of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 1 (2 Months of Age)

End point description:

Systemic events (any fever >=38 degrees Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1

category. Safety population: all subjects who received dose 1 of the infant series vaccination (2 months of age). (n)= number of subjects reporting yes for at least 1 day or no for all days.

End point type	Other pre-specified

End point timeframe:

Within 4 days after Dose 1 of the infant series (2 months of age)

End point values	Infant Series 13vPnc Dose 1	Infant Series 7vPnC Dose 1		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	83	84		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C	55	50		
Fever >39 but <=40 degrees C (n=74,74)	1.4	1.4		
Fever >40 degrees C (n=74,74)	0	0		
Decreased appetite	50	55.6		
Irritability	65	70		
Increased sleep	53.2	50.6		
Decreased sleep	44.3	41		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[103]
P-value	= 0.633
Method	Fisher exact

Notes:

[103] - The statistical analyses was descriptive.

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[104]
P-value	> 0.99
Method	Fisher exact

Notes:

[104] - The statistical analyses was descriptive.

Statistical analysis title	Fever >40 degrees C
Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[105]
P-value	= 99999 [106]
Method	Fisher exact

Notes:

[105] - The statistical analyses was descriptive.

[106] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with fever >40 degrees C either treatment group, p-value could not be estimated.

Statistical analysis title	Decreased appetite

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[107]
P-value	= 0.527
Method	Fisher exact

Notes:

[107] - The statistical analyses was descriptive.

Statistical analysis title	Irritability

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[108]
P-value	= 0.613
Method	Fisher exact

Notes:

[108] - The statistical analyses was descriptive.

Statistical analysis title	Increased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[109]
P-value	= 0.753
Method	Fisher exact

Notes:

[109] - The statistical analyses was descriptive.

Statistical analysis title	Decreased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 1 v Infant Series 7vPnC Dose 1
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	other[110]
P-value	= 0.748
Method	Fisher exact

Notes:

[110] - The statistical analyses was descriptive.

Other pre-specified: Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 2 (4 Months of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 2 (4 Months of Age)

End point description:

Systemic events (any fever >=38 degrees C, decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received the first 2 doses of the infant series vaccination (4 months of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after Dose 2 of the infant series (4 months of age)

End point values	Infant Series 13vPnc Dose 2	Infant Series 7vPnC Dose 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	80	84		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C	52.1	43.4		
Fever >39 but <=40 degrees C (n=69, 72)	2.9	2.8		
Fever >40 degrees C (n=69, 71)	0	0		
Decreased appetite	50.7	56.1		
Irritability	56	57.5		
Increased sleep	41.1	43.4		
Decreased sleep (n=71, 77)	42.3	32.5		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[111]
P-value	= 0.327
Method	Fisher exact

Notes:

[111] - The statistical analyses was descriptive.

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[112]
P-value	> 0.99
Method	Fisher exact

Notes:

[112] - The statistical analyses was descriptive.

Statistical analysis title	Fever >40 degrees C
Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[113]
P-value	= 99999 [114]
Method	Fisher exact

Notes:

[113] - The statistical analyses was descriptive.

[114] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with fever >40 degrees C in either treatment group, p-value could not be estimated.

Statistical analysis title	Decreased appetite

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[115]
P-value	= 0.522
Method	Fisher exact

Notes:

[115] - The statistical analyses was descriptive.

Statistical analysis title	Irritability

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[116]
P-value	= 0.872
Method	Fisher exact

Notes:

[116] - The statistical analyses was descriptive.

Statistical analysis title	Increased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[117]
P-value	= 0.868
Method	Fisher exact

Notes:

[117] - The statistical analyses was descriptive.

Statistical analysis title	Decreased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 2 v Infant Series 7vPnC Dose 2
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[118]
P-value	= 0.237
Method	Fisher exact

Notes:

[118] - The statistical analyses was descriptive.

Other pre-specified: Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 3 (6 Months of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Infant Series Dose 3 (6 Months of Age)

End point description:

Systemic events (any fever >=38 degrees C, decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received all 3 doses of the infant series vaccination (6 months of age). n=number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Other pre-specified

End point timeframe:

Within 4 days after dose 3 of the infant series (6 months of age)

End point values	Infant Series 13vPnc Dose 3	Infant Series 7vPnC Dose 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	80	84		
Units: percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C (n=66,66)	31.8	22.7		
Fever >39 but <=40 degrees C (n=65,66)	4.6	9.1		
Fever >40 degrees C (n=65,64)	0	1.6		
Decreased appetite (n=69,75)	43.5	52		
Irritability (n=68,71)	42.6	47.9		
Increased sleep (n=66,70)	40.9	37.1		
Decreased sleep (n=68,69)	30.9	33.3		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[119]
P-value	= 0.329
Method	Fisher exact

Notes:

[119] - The statistical analyses was descriptive.

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[120]
P-value	= 0.492
Method	Fisher exact

Notes:

[120] - The statistical analyses was descriptive.

Statistical analysis title	Fever >40 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[121]
P-value	= 0.496
Method	Fisher exact

Notes:

[121] - The statistical analyses was descriptive.

Statistical analysis title	Decreased appetite

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[122]
P-value	= 0.322
Method	Fisher exact

Notes:

[122] - The statistical analyses was descriptive.

Statistical analysis title	Irritability

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[123]
P-value	= 0.61
Method	Fisher exact

Notes:

[123] - The statistical analyses was descriptive.

Statistical analysis title	Increased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[124]
P-value	= 0.726
Method	Fisher exact

Notes:

[124] - The statistical analyses was descriptive.

Statistical analysis title	Decreased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Infant Series 13vPnc Dose 3 v Infant Series 7vPnC Dose 3

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[125]
P-value	= 0.855
Method	Fisher exact

Notes:

[125] - The statistical analyses was descriptive.

Post-hoc: Percentage of Subjects With Pre-specified Systemic Events: Toddler Dose (15 Months of Age)

End point title	Percentage of Subjects With Pre-specified Systemic Events: Toddler Dose (15 Months of Age)

End point description:

Systemic events (any fever >=38 degrees C, decreased appetite, irritability, increased sleep, decreased sleep) were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population: all subjects who received the toddler dose (15 months of age). n= number of subjects reporting yes for at least 1 day or no for all days for each treatment group respectively.

End point type	Post-hoc

End point timeframe:

Within 4 days after the toddler dose (15 months of age)

End point values	Toddler Series 13vPnC	Toddler Series 7vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	84		
Units: Percentage of Subjects				
number (not applicable)				
Fever >=38 but <=39 degrees C (n=65,70)	29.2	21.4		
Fever >39 but <=40 degrees C (n=63,69)	3.2	4.3		
Fever >40 degrees C (n=63,69)	0	0		
Decreased appetite (n=65,75)	27.7	30.7		
Irritability (n=65,74)	27.7	27		
Increased sleep (n=66,72)	16.7	16.7		
Decreased sleep (n=64,74)	17.2	23		

Statistical analyses

Statistical analysis title	Fever >=38 but <=39 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[126]
P-value	= 0.326
Method	Fisher exact

Notes:

[126] - The statistical analyses was descriptive.

Statistical analysis title	Fever >39 but <=40 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[127]
P-value	> 0.99
Method	Fisher exact

Notes:

[127] - The statistical analyses was descriptive.

Statistical analysis title	Fever >40 degrees C

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[128]
P-value	= 99999 [129]
Method	Fisher exact

Notes:

[128] - The statistical analyses was descriptive.

[129] - Here, 99999 in the p-value signifies "Not estimable". Since there were no subject with fever >40 degrees C in either treatment group, p-value could not be estimated.

Statistical analysis title	Decreased appetite

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[130]
P-value	= 0.714
Method	Fisher exact

Notes:

[130] - The statistical analyses was descriptive.

Statistical analysis title	Irritability

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[131]
P-value	> 0.99
Method	Fisher exact

Notes:

[131] - The statistical analyses was descriptive.

Statistical analysis title	Increased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[132]
P-value	> 0.99
Method	Fisher exact

Notes:

[132] - The statistical analyses was descriptive.

Statistical analysis title	Decreased sleep

Statistical analysis description:

Fisher exact test was used to calculate p-value.

Comparison groups	Toddler Series 13vPnC v Toddler Series 7vPnC
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	other[133]
P-value	= 0.525
Method	Fisher exact

Notes:

[133] - The statistical analyses was descriptive.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline through 1 month after last study vaccination (16 Months). Local reactions and systemic events assessed within 4 days of dose: Infant Series Dose 1=2 months of age; Dose 2=4 months of age; Dose 3=6 months of age; Toddler Dose=15 months of age

Adverse event reporting additional description:

An AE term may be reported as both a serious and non-serious AE, but are distinct events. AE may = serious for 1 subject and = non-serious for another subject or subject may have experienced both a serious and non-serious episode of the same event. LRs and SEs were to be assessed only for infant series and toddler dose groups.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	Infant Series 13vPnC

Reporting group description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: diphtheria, tetanus, and acellular pertussis (DTaP); inactivated poliovirus (IPV); and Haemophilus influenzae type b (Hib). At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and hepatitis B virus (HBV) vaccine.

Reporting group title	Infant Series 7vPnC

Reporting group description:

Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 7vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 7vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Reporting group title	After Infant Series 13vPnC

Reporting group description:

Included subjects who received 1 single dose of 13vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Reporting group title	After Infant Series 7vPnC

Reporting group description:

Included subjects who received 1 single dose of 7vPnC, administered intramuscularly, at 2, 4 and 6 months of age (infant series). At 2 and 4 months of age during the infant series, 13vPnC was co-administered with a commercially available combination vaccine containing: DTaP; IPV; and Hib. At 6 months of age during the infant series, 13vPnC was co-administered with DTaP-IPV-Hib and HBV vaccine.

Reporting group title	Toddler Series 13vPnC

Reporting group description:

Subjects received 1 single dose of 13vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Reporting group title	Toddler Series 7vPnC

Reporting group description:

Subjects received 1 single dose of 7vPnC, administered intramuscularly, at 15 months of age (toddler dose).

Serious adverse events	Infant Series 13vPnC	Infant Series 7vPnC	After Infant Series 13vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 83 (4.82%)	4 / 84 (4.76%)	12 / 83 (14.46%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ileus			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (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
Inguinal hernia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal functional disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Testicular retraction			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (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
Renal and urinary disorders			
Hydronephrosis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 83 (0.00%)	3 / 84 (3.57%)	2 / 83 (2.41%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 83 (1.20%)	1 / 84 (1.19%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	2 / 83 (2.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia primary atypical			

subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (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 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	2 / 83 (2.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Roseola			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	After Infant Series 7vPnC	Toddler Series 13vPnC	Toddler Series 7vPnC
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 84 (10.71%)	0 / 80 (0.00%)	3 / 84 (3.57%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	2 / 84 (2.38%)	0 / 80 (0.00%)	0 / 84 (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

Gastrointestinal disorders			
Ileus			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Inguinal hernia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Intestinal functional disorder			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue disorder			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Reproductive system and breast disorders			
Testicular retraction			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (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
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Nephritis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			

subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 84 (2.38%)	0 / 80 (0.00%)	0 / 84 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Urinary tract infection			

subjects affected / exposed	3 / 84 (3.57%)	0 / 80 (0.00%)	0 / 84 (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
Croup infectious			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (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
Otitis media acute			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (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
Roseola			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (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
Acute tonsillitis			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			

subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Sinusitis			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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
Hypovolaemia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (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

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

Non-serious adverse events	Infant Series 13vPnC	Infant Series 7vPnC	After Infant Series 13vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	81 / 83 (97.59%)	77 / 84 (91.67%)	11 / 83 (13.25%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 83 (6.02%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	6	2	0
Fever >= 38 degrees C but <= 39 degrees C Infant Series Dose 1 and Toddler Dose			
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	44 / 80 (55.00%)	39 / 78 (50.00%)	0 / 83 (0.00%)
occurrences (all)	44	39	0
Fever > 39 degrees C but <= 40 degrees C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[2] occurrences (all)	1 / 74 (1.35%) 1	1 / 74 (1.35%) 1	0 / 83 (0.00%) 0
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[3] occurrences (all)	52 / 80 (65.00%) 52	56 / 80 (70.00%) 56	0 / 83 (0.00%) 0
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic event 0.0 alternative assessment type: Systematic subjects affected / exposed[4] occurrences (all)	41 / 77 (53.25%) 41	41 / 81 (50.62%) 41	0 / 83 (0.00%) 0
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	35 / 79 (44.30%) 35	32 / 78 (41.03%) 32	0 / 83 (0.00%) 0
Fever >= 38 degrees C but <= 39 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[6] occurrences (all)	38 / 73 (52.05%) 38	33 / 76 (43.42%) 33	0 / 83 (0.00%) 0
Fever > 39 degrees C but <= 40 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[7]	2 / 69 (2.90%)	2 / 72 (2.78%)	0 / 83 (0.00%)
occurrences (all)	2	2	0
Fever >= 38 degrees C but <= 39 degrees C nfant Series Dose 3			
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	21 / 66 (31.82%)	15 / 66 (22.73%)	0 / 83 (0.00%)
occurrences (all)	21	15	0
Fever > 39 degrees C but <= 40 degrees C Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	3 / 65 (4.62%)	6 / 66 (9.09%)	0 / 83 (0.00%)
occurrences (all)	3	6	0
Decreased appetite Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	37 / 73 (50.68%)	46 / 82 (56.10%)	0 / 83 (0.00%)
occurrences (all)	37	46	0
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	42 / 75 (56.00%)	46 / 80 (57.50%)	0 / 83 (0.00%)
occurrences (all)	42	46	0
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	30 / 73 (41.10%)	33 / 76 (43.42%)	0 / 83 (0.00%)
occurrences (all)	30	33	0
Decreased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	30 / 71 (42.25%) 30	25 / 77 (32.47%) 25	0 / 83 (0.00%) 0
Fever > 40 degrees C Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	0 / 65 (0.00%) 0	1 / 64 (1.56%) 1	0 / 83 (0.00%) 0
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[15] occurrences (all)	30 / 69 (43.48%) 30	39 / 75 (52.00%) 39	0 / 83 (0.00%) 0
Irritability Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	29 / 68 (42.65%) 29	34 / 71 (47.89%) 34	0 / 83 (0.00%) 0
Increased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[17] occurrences (all)	27 / 66 (40.91%) 27	26 / 70 (37.14%) 26	0 / 83 (0.00%) 0
Decreased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[18]	21 / 68 (30.88%)	23 / 69 (33.33%)	0 / 83 (0.00%)
occurrences (all)	21	23	0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 83 (2.41%)	1 / 84 (1.19%)	1 / 83 (1.20%)
occurrences (all)	2	1	1
Rhinitis allergic			
subjects affected / exposed	5 / 83 (6.02%)	4 / 84 (4.76%)	1 / 83 (1.20%)
occurrences (all)	5	5	1
Rhinorrhoea			
subjects affected / exposed	4 / 83 (4.82%)	2 / 84 (2.38%)	1 / 83 (1.20%)
occurrences (all)	5	2	1
Cough			
subjects affected / exposed	1 / 83 (1.20%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	1	2	0
Allergic respiratory disease			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Tonsillar inflammation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic			

disorders			
Dacryostenosis congenital			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Nervous system disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Eye disorders			
Dacryostenosis acquired			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 83 (1.20%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	1	2	0
Constipation			
subjects affected / exposed	2 / 83 (2.41%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	2	1	0
Enteritis			
subjects affected / exposed	1 / 83 (1.20%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	1	1	0
Gastric disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Intestinal functional disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0

Peptic ulcer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	2 / 83 (2.41%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	2	0	0
Flatulence			
subjects affected / exposed	2 / 83 (2.41%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	3	0	0
Irritable bowel syndrome			
subjects affected / exposed	2 / 83 (2.41%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	0 / 83 (0.00%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	0	2	0
Abdominal distension			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Jaundice			

subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	10 / 83 (12.05%)	11 / 84 (13.10%)	5 / 83 (6.02%)
occurrences (all)	10	12	6
Dermatitis diaper			
subjects affected / exposed	5 / 83 (6.02%)	6 / 84 (7.14%)	0 / 83 (0.00%)
occurrences (all)	7	6	0
Dermatitis contact			
subjects affected / exposed	3 / 83 (3.61%)	5 / 84 (5.95%)	3 / 83 (3.61%)
occurrences (all)	3	5	3
Dermatitis			
subjects affected / exposed	2 / 83 (2.41%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	2	1	0
Dermatitis atopic			
subjects affected / exposed	1 / 83 (1.20%)	3 / 84 (3.57%)	1 / 83 (1.20%)
occurrences (all)	1	3	1
Urticaria			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	1	0	1
Rash			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	1	0	1
Rash papular			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Heat rash			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 83 (1.20%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	1	1	0

Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	25 / 80 (31.25%)	26 / 76 (34.21%)	0 / 83 (0.00%)
occurrences (all)	25	26	0
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	4 / 75 (5.33%)	7 / 75 (9.33%)	0 / 83 (0.00%)
occurrences (all)	4	7	0
Swelling (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	20 / 78 (25.64%)	9 / 76 (11.84%)	0 / 83 (0.00%)
occurrences (all)	20	9	0
Swelling (Mild) = 0.5 to 2.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	19 / 78 (24.36%)	9 / 76 (11.84%)	0 / 83 (0.00%)
occurrences (all)	19	9	0
Swelling (Moderate) = 2.5 to 7.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	1 / 74 (1.35%)	0 / 74 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Redness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[24]	23 / 77 (29.87%)	22 / 76 (28.95%)	0 / 83 (0.00%)
occurrences (all)	23	22	0
Redness (Mild) = 0.5 to 2.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	20 / 77 (25.97%)	20 / 76 (26.32%)	0 / 83 (0.00%)
occurrences (all)	20	20	0
Redness (Moderate) = 2.5 to 7.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	6 / 74 (8.11%)	2 / 74 (2.70%)	0 / 83 (0.00%)
occurrences (all)	6	2	0
Tenderness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	17 / 72 (23.61%)	17 / 76 (22.37%)	0 / 83 (0.00%)
occurrences (all)	17	17	0
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	2 / 69 (2.90%)	1 / 71 (1.41%)	0 / 83 (0.00%)
occurrences (all)	2	1	0
Swelling (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	9 / 70 (12.86%)	11 / 72 (15.28%)	0 / 83 (0.00%)
occurrences (all)	9	11	0
Swelling (Mild) = 0.5 to 2.0 cm Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[30] occurrences (all)	9 / 70 (12.86%) 9	11 / 72 (15.28%) 11	0 / 83 (0.00%) 0
Redness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[31] occurrences (all)	12 / 70 (17.14%) 12	15 / 74 (20.27%) 15	0 / 83 (0.00%) 0
Redness (Mild) = 0.5 to 2.0 cm Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[32] occurrences (all)	12 / 70 (17.14%) 12	13 / 74 (17.57%) 13	0 / 83 (0.00%) 0
Redness (Moderate) = 2.5 to 7.0 cm Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[33] occurrences (all)	0 / 69 (0.00%) 0	2 / 71 (2.82%) 2	0 / 83 (0.00%) 0
Tenderness (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[34] occurrences (all)	13 / 67 (19.40%) 13	12 / 67 (17.91%) 12	0 / 83 (0.00%) 0
Tenderness (Significant) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed[35]	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Swelling (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	11 / 65 (16.92%)	3 / 65 (4.62%)	0 / 83 (0.00%)
occurrences (all)	11	3	0
Swelling (Mild) = 0.5 to 2.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	10 / 65 (15.38%)	3 / 65 (4.62%)	0 / 83 (0.00%)
occurrences (all)	10	3	0
Swelling (Moderate) = 2.5 to 7.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	2 / 65 (3.08%)	0 / 64 (0.00%)	0 / 83 (0.00%)
occurrences (all)	2	0	0
Redness (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	14 / 67 (20.90%)	9 / 65 (13.85%)	0 / 83 (0.00%)
occurrences (all)	14	9	0
Redness (Mild) = 0.5 to 2.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	12 / 66 (18.18%)	9 / 65 (13.85%)	0 / 83 (0.00%)
occurrences (all)	12	9	0
Redness (Moderate) = 2.5 to 7.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	3 / 66 (4.55%)	0 / 64 (0.00%)	0 / 83 (0.00%)
occurrences (all)	3	0	0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	39 / 78 (50.00%)	45 / 81 (55.56%)	0 / 83 (0.00%)
occurrences (all)	39	45	0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Scleroderma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Torticollis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	31 / 83 (37.35%)	53 / 84 (63.10%)	0 / 83 (0.00%)
occurrences (all)	45	90	0
Bronchiolitis			
subjects affected / exposed	4 / 83 (4.82%)	4 / 84 (4.76%)	0 / 83 (0.00%)
occurrences (all)	4	5	0
Bronchitis			
subjects affected / exposed	7 / 83 (8.43%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	8	2	0
Gastroenteritis			
subjects affected / exposed	2 / 83 (2.41%)	5 / 84 (5.95%)	0 / 83 (0.00%)
occurrences (all)	2	5	0
Diarrhoea infectious			

subjects affected / exposed	2 / 83 (2.41%)	4 / 84 (4.76%)	0 / 83 (0.00%)
occurrences (all)	2	4	0
Oral herpes			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Pneumonia bacterial			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 83 (0.00%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	0	2	0
Acute tonsillitis			
subjects affected / exposed	1 / 83 (1.20%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	1	1	0
Acute sinusitis`			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 83 (0.00%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	0	3	0
Pharyngitis			
subjects affected / exposed	1 / 83 (1.20%)	3 / 84 (3.57%)	0 / 83 (0.00%)
occurrences (all)	1	3	0
Roseola			
subjects affected / exposed	3 / 83 (3.61%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	3	1	0
Tonsillitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 83 (1.20%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	1	3	0
Abscess limb			

subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Bacteriuria			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	2	0
Bronchopneumonia			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Croup infectious			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Exanthema subitum			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	1 / 83 (1.20%)	0 / 84 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	2 / 83 (2.41%)	2 / 84 (2.38%)	0 / 83 (0.00%)
occurrences (all)	2	2	0
Pneumonia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	0 / 83 (0.00%)	1 / 84 (1.19%)	0 / 83 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	After Infant Series 7vPnC	Toddler Series 13vPnC	Toddler Series 7vPnC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 84 (19.05%)	39 / 80 (48.75%)	47 / 84 (55.95%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 84 (0.00%)	2 / 80 (2.50%)	2 / 84 (2.38%)
occurrences (all)	0	2	2
Fever >= 38 degrees C but <= 39 degrees C Infant Series Dose 1 and Toddler Dose			
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 84 (0.00%)	19 / 65 (29.23%)	15 / 70 (21.43%)
occurrences (all)	0	19	15
Fever > 39 degrees C but <= 40 degrees C Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 84 (0.00%)	2 / 63 (3.17%)	3 / 69 (4.35%)
occurrences (all)	0	2	3
Irritability Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 84 (0.00%)	18 / 65 (27.69%)	20 / 74 (27.03%)
occurrences (all)	0	18	20
Increased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic event 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[4]	0 / 84 (0.00%)	11 / 66 (16.67%)	12 / 72 (16.67%)
occurrences (all)	0	11	12
Decreased sleep Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 84 (0.00%)	11 / 64 (17.19%)	17 / 74 (22.97%)
occurrences (all)	0	11	17
Fever >= 38 degrees C but <= 39 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Fever > 39 degrees C but <= 40 degrees C Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Fever >= 38 degrees C but <= 39 degrees C nfant Series Dose 3			
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Fever > 39 degrees C but <= 40 degrees C Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Decreased appetite Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Irritability Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Increased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Decreased sleep Infant Series Dose 2	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Fever > 40 degrees C Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Decreased appetite Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic			

subjects affected / exposed[15]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Irritability Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Increased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Decreased sleep Infant Series Dose 3	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 84 (1.19%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	2	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 84 (0.00%)	2 / 80 (2.50%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
Cough			

subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Allergic respiratory disease			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Tonsillar inflammation			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Skin laceration			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Dacryostenosis congenital			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Nervous system disorder			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dacryostenosis acquired			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Colitis			

subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Enteritis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Intestinal functional disorder			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Peptic ulcer			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Eructation			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	11 / 84 (13.10%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences (all)	12	0	1
Dermatitis diaper			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
Dermatitis contact			
subjects affected / exposed	7 / 84 (8.33%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences (all)	8	0	1
Dermatitis			
subjects affected / exposed	1 / 84 (1.19%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
Dermatitis atopic			

subjects affected / exposed	3 / 84 (3.57%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	3	0	0
Urticaria			
subjects affected / exposed	2 / 84 (2.38%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Heat rash			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 84 (0.00%)	7 / 64 (10.94%)	17 / 75 (22.67%)
occurrences (all)	0	7	17
Tenderness (Significant) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 84 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 84 (0.00%)	5 / 63 (7.94%)	4 / 70 (5.71%)
occurrences (all)	0	5	4
Swelling (Mild) = 0.5 to 2.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 84 (0.00%)	4 / 63 (6.35%)	4 / 70 (5.71%)
occurrences (all)	0	4	4
Swelling (Moderate) = 2.5 to 7.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 84 (0.00%)	1 / 63 (1.59%)	0 / 69 (0.00%)
occurrences (all)	0	1	0
Redness (Any) Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 84 (0.00%)	10 / 65 (15.38%)	9 / 70 (12.86%)
occurrences (all)	0	10	9
Redness (Mild) = 0.5 to 2.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 84 (0.00%)	9 / 65 (13.85%)	9 / 70 (12.86%)
occurrences (all)	0	9	9
Redness (Moderate) = 2.5 to 7.0 cm Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 84 (0.00%)	1 / 63 (1.59%)	0 / 69 (0.00%)
occurrences (all)	0	1	0
Tenderness (Any) Infant Series Dose	Additional description: Subjects affected and occurrences for LRs is same as		

2	data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Tenderness (Significant) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[28] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Swelling (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[29] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Swelling (Mild) = 0.5 to 2.0 cm Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[30] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Redness (Any) Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[31] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Redness (Mild) = 0.5 to 2.0 cm Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic			

subjects affected / exposed[32]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Redness (Moderate) = 2.5 to 7.0 cm Infant Series Dose 2	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Tenderness (Significant) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Swelling (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Swelling (Mild) = 0.5 to 2.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Swelling (Moderate) = 2.5 to 7.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		

alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Redness (Any) Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Redness (Mild) = 0.5 to 2.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[40] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Redness (Moderate) = 2.5 to 7.0 cm Infant Series Dose 3	Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Local Reaction 0.0 alternative assessment type: Systematic subjects affected / exposed[41] occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Decreased appetite Infant Series Dose 1 and Toddler Dose	Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version.		
alternative dictionary used: Systemic Event 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	0 / 84 (0.00%) 0	18 / 65 (27.69%) 18	23 / 75 (30.67%) 23
Renal and urinary disorders			
Hydronephrosis subjects affected / exposed occurrences (all)	0 / 84 (0.00%) 0	0 / 80 (0.00%) 0	0 / 84 (0.00%) 0
Musculoskeletal and connective tissue disorders			

Scleroderma			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 84 (0.00%)	9 / 80 (11.25%)	8 / 84 (9.52%)
occurrences (all)	0	10	8
Bronchiolitis			
subjects affected / exposed	1 / 84 (1.19%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
Bronchitis			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 84 (1.19%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	2 / 84 (2.38%)
occurrences (all)	0	1	2
Acute tonsillitis			

subjects affected / exposed	0 / 84 (0.00%)	2 / 80 (2.50%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
Acute sinusitis`			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Roseola			
subjects affected / exposed	0 / 84 (0.00%)	1 / 80 (1.25%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Abscess limb			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			

subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 84 (0.00%)	0 / 80 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 February 2008	1. The investigators and parents/legal guardians was allowed to take tympanic temperatures instead of axillary temperatures, as this reflected standard practice in Taiwan. 2. At visit 3, for concomitant vaccination, a combination vaccine DTaP-IPV-Hib-HBV was given instead of 2 single injections of DTaP-IPV-Hib and HBV.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Geometric Mean Concentration Outcome Measures were identified as secondary analysis in the study protocol, but are included to maintain consistency with other postings for this program.

Notes: