Clinical trial results:
A Phase 3, Open-Label Trial Evaluating the Safety, Tolerability, and Immunogenicity of a 13-valent Pneumococcal Conjugate Vaccine in Older Infants and Children Who Are Naive to Previous Vaccination With Pneumococcal Conjugate Vaccine

Summary

EudraCT number	2006-006779-19
Trial protocol	PL
Global end of trial date	31 March 2008

Results information

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

Trial information

Trial identification

Sponsor protocol code	6096A1-3002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00452452
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000036-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 September 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 March 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objective:
To assess the pneumococcal immune responses induced by 13vPnC when measured 1 month after last scheduled dose of 13vPnC in each age group.

Protection of trial subjects:

The study was in compliance with with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation (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	12 July 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 355
Worldwide total number of subjects	355
EEA total number of subjects	355

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)	202
Children (2-11 years)	153
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study started on 12 July 2007 and ended on 31 March 2008. Overall, 355 subjects were enrolled in Poland.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC 7 to <12 Months of Age

Arm description:

Subjects 7 to less than (<) 12 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 3 doses of 13-valent pneumococcal conjugate vaccine (13vPnC); the first two at least 28 days apart (infant series) and the third single IM 0.5 mL dose of 13vPnC at 12 to 16 months of age (toddler dose), at least 46 days after last infant dose.

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

Dosage and administration details:

Three single intramuscular (IM) 0.5 milliliter (mL) doses of 13-valent pneumococcal conjugate vaccine (13vPnC); the first two at least 28 days apart (infant series) and the third single IM 0.5 mL dose of 13vPnC at 12 to 16 months of age (toddler dose), at least 46 days after last infant dose.

Arm title	13vPnC 12 to <24 Months of Age

Arm description:

Subjects 12 to <24 months of age with 0 prior dose of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 2 single doses of 13vPnC at least 56 days apart.

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

Dosage and administration details:

Two single intramuscular (IM) 0.5 milliliter (mL) doses of 13-valent pneumococcal conjugate vaccine (13vPnC); at least 56 days after the first dose.

Arm title	13vPnC 24 to <72 Months of Age

Arm description:

Subjects 24 to <72 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a single dose of 13vPnC.

Arm type	Experimental

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

Dosage and administration details:

A single intramuscular (IM) 0.5 milliliter (mL) doses of 13-valent pneumococcal conjugate vaccine (13vPnC).

Number of subjects in period 1	13vPnC 7 to <12 Months of Age	13vPnC 12 to <24 Months of Age	13vPnC 24 to <72 Months of Age
Started	90	112	153
Vaccinated Dose 1	90	112	152
Vaccinated Dose 2	90	112	0 [1]
Vaccinated Dose 3	89	0 [2]	0 [3]
Completed	88	112	152
Not completed	2	0	1
Consent withdrawn by subject	1	-	-
Protocol Violation	-	-	1
Lost to follow-up	1	-	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subject was administered dose 2 for this arm.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subject was administered dose 3 for this arm.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No subject was administered dose 3 for this arm.

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC 7 to <12 Months of Age
Reporting group description:	
Subjects 7 to less than (<) 12 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 3 doses of 13-valent pneumococcal conjugate vaccine (13vPnC); the first two at least 28 days apart (infant series) and the third single IM 0.5 mL dose of 13vPnC at 12 to 16 months of age (toddler dose), at least 46 days after last infant dose.	
Reporting group title	13vPnC 12 to <24 Months of Age
Reporting group description:	
Subjects 12 to <24 months of age with 0 prior dose of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 2 single doses of 13vPnC at least 56 days apart.	
Reporting group title	13vPnC 24 to <72 Months of Age
Reporting group description:	
Subjects 24 to <72 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a single dose of 13vPnC.	

Reporting group values	13vPnC 7 to <12 Months of Age	13vPnC 12 to <24 Months of Age	13vPnC 24 to <72 Months of Age
Number of subjects	90	112	153
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	8.7	17.6	42
standard deviation	± 1.6	± 3.5	± 13.1
Gender categorical Units: Subjects			
Female	47	58	74
Male	43	54	79

Reporting group values	Total		
Number of subjects	355		
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	179		
Male	176		

End points

End points reporting groups

Reporting group title	13vPnC 7 to <12 Months of Age
Reporting group description:	
Subjects 7 to less than (<) 12 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 3 doses of 13-valent pneumococcal conjugate vaccine (13vPnC); the first two at least 28 days apart (infant series) and the third single IM 0.5 mL dose of 13vPnC at 12 to 16 months of age (toddler dose), at least 46 days after last infant dose.	
Reporting group title	13vPnC 12 to <24 Months of Age
Reporting group description:	
Subjects 12 to <24 months of age with 0 prior dose of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 2 single doses of 13vPnC at least 56 days apart.	
Reporting group title	13vPnC 24 to <72 Months of Age
Reporting group description:	
Subjects 24 to <72 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a single dose of 13vPnC.	
Subject analysis set title	13vPnC Group 1 - Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects 7 to <12 months of age with 0 prior doses of Prevnar received a single intramuscular (IM) 0.5 milliliter (mL) dose of vaccine 13vPnC in the infant series.	
Subject analysis set title	13vPnC Group 2 - Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects 12 to <24 months of age with 0 prior doses of Prevnar received a single IM 0.5 mL dose of 13vPnC in the infant series.	
Subject analysis set title	13vPnC Group 3 - Dose 1
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects 24 to <72 months of age with 0 prior doses of Prevnar received a single IM 0.5 mL dose of 13vPnC in the infant series.	
Subject analysis set title	13vPnC Group 1 - Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects 7 to less than (<) 12 months of age received a second single IM 0.5 milliliter (mL) dose of 13vPnC at least 28 days after the first in the infant series.	
Subject analysis set title	13vPnC Group 2 - Dose 2
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects 12 to <24 months of age received a second single IM 0.5 mL doses of 13vPnC at least 56 days from the first (infant series).	
Subject analysis set title	13vPnC Group 1 - Dose 3
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects received a third single IM 0.5 mL dose of 13vPnC at 12 to 16 months of age (toddler dose), at least 46 days after last infant dose.	

Primary: Percentage of Subjects Achieving Antibody Level Greater Than Equal To (>=) 0.35 Microgram per Mililiter µg/mL After Vaccination

End point title	Percentage of Subjects Achieving Antibody Level Greater Than Equal To (>=) 0.35 Microgram per Mililiter µg/mL After Vaccination[1]
End point description:	
Percentages of subjects achieving World Health Organization (WHO) predefined antibody threshold >=0.	

35µg/mL along with the corresponding 95 percent (%) 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 (per protocol) population who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations. (n) = number of subjects with a determinate immunoglobulin G (IgG) antibody concentration to the given serotype.

End point type	Primary

End point timeframe:

28 to 42 days after vaccination 3 for Group 1 (13 to <17 months of age), after vaccination 2 for Group 2 (14 to <26 months of age), and after vaccination 1 for Group 3 (26 to <73 months of age)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Inferential statistical analysis was not performed since descriptive statistical analysis was planned for this endpoint.

End point values	13vPnC 7 to <12 Months of Age	13vPnC 12 to <24 Months of Age	13vPnC 24 to <72 Months of Age	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	84	110	152	
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotypes - Serotype 4 (n= 84,110,151)	100 (95.7 to 100)	100 (96.7 to 100)	99.3 (96.4 to 100)	
Common Serotypes - Serotype 6B (n=83,110,150)	98.8 (93.5 to 100)	100 (96.7 to 100)	99.3 (96.3 to 100)	
Common Serotypes - Serotype 9V (n= 83,104,148)	98.8 (93.5 to 100)	99 (94.8 to 100)	98.6 (95.2 to 99.8)	
Common Serotypes - Serotype 14 (n= 84,108,135)	100 (95.7 to 100)	100 (96.6 to 100)	88.1 (81.5 to 93.1)	
Common Serotypes - Serotype 18C (n= 83,109,151)	100 (95.7 to 100)	100 (96.7 to 100)	98.7 (95.3 to 99.8)	
Common Serotypes - Serotype 19F (n=84,110,147)	97.6 (91.7 to 99.7)	100 (96.7 to 100)	98 (94.2 to 99.6)	
Common Serotypes - Serotype 23F (n= 84,110,151)	98.8 (93.5 to 100)	92.7 (86.2 to 96.8)	93.4 (88.2 to 96.8)	
Additional Serotypes - Serotype 1 (n= 83,108,149)	100 (95.7 to 100)	100 (96.6 to 100)	96.6 (92.3 to 98.9)	
Additional Serotypes - Serotype 3 (n= 83,108,149)	98.8 (93.5 to 100)	100 (96.6 to 100)	97.3 (93.3 to 99.3)	
Additional Serotypes - Serotype 5 (n= 84,107,152)	97.6 (91.7 to 99.7)	99.1 (94.9 to 100)	98.7 (95.3 to 99.8)	
Additional Serotypes - Serotype 6A (n= 84,110,150)	100 (95.7 to 100)	98.2 (93.6 to 99.8)	100 (97.6 to 100)	
Additional Serotypes - Serotype 7F (n= 84,108,142)	100 (95.7 to 100)	100 (96.6 to 100)	99.3 (96.1 to 100)	
Additional Serotypes - Serotype 19A (n=84,110,150)	100 (95.7 to 100)	100 (96.7 to 100)	100 (97.6 to 100)	

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Antibody Concentration (GMC) After Vaccination in 13vPnC Groups

End point title	Geometric Mean Antibody Concentration (GMC) After

	Vaccination in 13vPnC Groups[2]

End point description:

GMC as measured by enzyme-linked immunosorbent assay (ELISA) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. The evaluable immunogenicity (per protocol) population was the primary analysis population consisting of eligible subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

End point type	Primary

End point timeframe:

28 to 42 days after vaccination 3 for Group 1 (13 to <17 months of age), after vaccination 2 for Group 2 (14 to <26 months of age), and after vaccination 1 for Group 3 (26 to <73 months of age)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Inferential statistical analysis was not performed since descriptive statistical analysis was planned for this endpoint.

End point values	13vPnC 7 to <12 Months of Age	13vPnC 12 to <24 Months of Age	13vPnC 24 to <72 Months of Age	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	84	110	152	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Common Serotypes - Serotype 4	3.63 (3.11 to 4.23)	4.28 (3.78 to 4.86)	3.37 (2.95 to 3.85)	
Common Serotypes - Serotype 6B	4.77 (3.9 to 5.84)	3.38 (2.81 to 4.06)	3.41 (2.8 to 4.16)	
Common Serotypes - Serotype 9V	2.56 (2.21 to 2.96)	3.08 (2.69 to 3.53)	2.67 (2.32 to 3.07)	
Common Serotypes - Serotype 14	8.04 (6.95 to 9.3)	6.45 (5.48 to 7.59)	2.24 (1.71 to 2.93)	
Common Serotypes - Serotype 18C	2.77 (2.39 to 3.23)	3.71 (3.29 to 4.19)	2.56 (2.17 to 3.03)	
Common Serotypes - Serotype 19F	2.88 (2.35 to 3.54)	3.07 (2.68 to 3.51)	2.53 (2.14 to 2.99)	
Common Serotypes - Serotype 23F	2.16 (1.82 to 2.55)	1.98 (1.64 to 2.39)	1.55 (1.31 to 1.85)	
Additional Serotypes - Serotype 1	2.88 (2.44 to 3.39)	2.74 (2.37 to 3.16)	1.78 (1.52 to 2.08)	
Additional Serotypes - Serotype 3	1.94 (1.68 to 2.24)	1.86 (1.6 to 2.15)	1.42 (1.23 to 1.64)	
Additional Serotypes - Serotype 5	2.85 (2.34 to 3.46)	2.16 (1.89 to 2.47)	2.33 (2.05 to 2.64)	
Additional Serotypes - Serotype 6A	3.72 (3.12 to 4.45)	2.62 (2.25 to 3.06)	2.96 (2.52 to 3.47)	
Additional Serotypes - Serotype 7F	5.3 (4.54 to 6.18)	5.99 (5.4 to 6.65)	4.92 (4.26 to 5.68)	
Additional Serotypes - Serotype 19A	4.77 (4.28 to 5.33)	4.94 (4.31 to 5.65)	6.03 (5.22 to 6.97)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting Pre-Specified Local Reactions

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

End point description:

Local reactions were collected 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 or redness present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (greater than [>] 7.0 cm). Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine.

End point type	Secondary

End point timeframe:

During the 4-day period after each dose

End point values	13vPnC Group 1 - Dose 1	13vPnC Group 2 - Dose 1	13vPnC Group 3 - Dose 1	13vPnC Group 1 - Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	90	112	152	90
Units: percentage of subjects				
number (not applicable)				
Tenderness - Any	15.1	33.3	42.3	15.1
Tenderness - Significant	1.2	0	4.1	3.5
Swelling - Any	36	44.5	36.9	32.2
Swelling - Mild	32.6	36.7	28.2	28.7
Swelling - Moderate	11.6	24.8	20.3	14
Swelling - Severe	0	0	0	0
Redness - Any	48.8	70	50	46
Redness - Mild	41.9	55.5	37.4	40.2
Redness - Moderate	16.3	38.2	25.7	9.3
Redness - Severe	0	0	0	0

End point values	13vPnC Group 2 - Dose 2	13vPnC Group 1 - Dose 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	112	89		
Units: percentage of subjects				
number (not applicable)				
Tenderness - Any	43.7	15.2		
Tenderness - Significant	4.1	6.4		
Swelling - Any	41	25		
Swelling - Mild	36.2	20.5		
Swelling - Moderate	12.1	11.3		
Swelling - Severe	0	0		
Redness - Any	54.7	37.8		
Redness - Mild	44.7	31.3		
Redness - Moderate	25.5	12.5		
Redness - Severe	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting Pre-Specified Systemic Events

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

End point description:

Systemic events (fever >=37.5 degrees Celsius [C], fever >=38 C but less than equal to <=39 C, fever >39 C but <=40 C, fever >40 C, decreased appetite, irritability, increased sleep, decreased sleep, hives, use of medication to treat symptoms, and use of medication to prevent symptoms) were reported using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine.

End point type	Secondary

End point timeframe:

During the 4-day period after each dose

End point values	13vPnC Group 1 - Dose 1	13vPnC Group 2 - Dose 1	13vPnC Group 3 - Dose 1	13vPnC Group 1 - Dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	90	112	152	90
Units: percentage of subjects				
number (not applicable)				
Fever ≥38°C but ≤39°C	3.4	3.7	0.7	8.1
Fever >39°C but ≤40°C	1.2	0.9	0.7	2.3
Fever >40°C	0	0	0	0
Decreased appetite	19.5	22.2	16.3	17.2
Irritability	24.1	30.6	14.3	34.5
Increased sleep	9.2	13	11.6	9.3
Decreased sleep	24.1	19.4	6.8	18.4
Use of antipyretic medication to treat symptoms	9.2	10.1	2.7	9.3
Use of antipyretic medication to prevent symptoms	8	13.8	4.8	4.7

End point values	13vPnC Group 2 - Dose 2	13vPnC Group 1 - Dose 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	112	89		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38°C but ≤39°C	5.1	5.1		

Fever >39°C but ≤40°C	0	1.3		
Fever >40°C	0	0		
Decreased appetite	25.5	17.5		
Irritability	34	24.7		
Increased sleep	10.1	2.6		
Decreased sleep	20.4	15		
Use of antipyretic medication to treat symptoms	13.3	7.6		
Use of antipyretic medication to prevent symptoms	14.3	5.1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Signing of the informed consent form (ICF) to the subject's last visit (28 to 42 days after the last dose of 13vPnC)

Adverse event reporting additional description:

An event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a AE and SAE event during the study. MedDra version was not captured hence 0.0 has been mentioned for dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC 7 to <12 Months of Age

Reporting group description:

Subjects 7 to <12 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 3 single doses of 13-valent pneumococcal conjugate vaccine (13vPnC); the first two at least 28 days apart (infant series) and the third single dose of 13vPnC at 12 to 16 months of age (toddler dose), at least 46 days after last infant dose.

Reporting group title	13vPnC 12 to <24 Months of Age

Reporting group description:

Subjects 12 to < 24 months of age with 0 prior dose of 7-valent pneumococcal conjugate vaccine (Prevnar) received a total of 2 doses of 13vPnC at least 56 days apart.

Reporting group title	13vPnC 24 to < 72 Months of Age

Reporting group description:

Subjects 24 to < 72 months of age with 0 prior doses of 7-valent pneumococcal conjugate vaccine (Prevnar) received a single dose of 13vPnC.

Serious adverse events	13vPnC 7 to <12 Months of Age	13vPnC 12 to <24 Months of Age	13vPnC 24 to < 72 Months of Age
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 90 (4.44%)	2 / 112 (1.79%)	2 / 152 (1.32%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			

subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (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
Stomatitis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (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
Dyspepsia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
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			
Exanthema subitum			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (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
Pharyngitis			

subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	1 / 152 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	13vPnC 7 to <12 Months of Age	13vPnC 12 to <24 Months of Age	13vPnC 24 to < 72 Months of Age
Total subjects affected by non-serious adverse events			
subjects affected / exposed	55 / 90 (61.11%)	83 / 112 (74.11%)	102 / 152 (67.11%)
Investigations			
Urological examination abnormal			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Upper limb fracture			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 90 (4.44%)	2 / 112 (1.79%)	1 / 152 (0.66%)
occurrences (all)	4	2	1
Injection site nodule			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Injection site pain			

subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Fever ≥38 degree centigrade (°C) but ≤39°C Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	3 / 87 (3.45%)	4 / 108 (3.70%)	1 / 147 (0.68%)
occurrences (all)	3	4	1
Fever >39°C but ≤40°C Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	1 / 86 (1.16%)	1 / 108 (0.93%)	1 / 147 (0.68%)
occurrences (all)	1	1	1
Decreased appetite Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	17 / 87 (19.54%)	24 / 108 (22.22%)	24 / 147 (16.33%)
occurrences (all)	17	24	24
Irritability Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	21 / 87 (24.14%)	33 / 108 (30.56%)	21 / 147 (14.29%)
occurrences (all)	21	33	21
Increased sleep Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	8 / 87 (9.20%)	14 / 108 (12.96%)	17 / 147 (11.56%)
occurrences (all)	8	14	17
Decreased sleep Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[6]	21 / 87 (24.14%)	21 / 108 (19.44%)	10 / 148 (6.76%)
occurrences (all)	21	21	10
Fever ≥38°C but ≤39°C Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	7 / 86 (8.14%)	5 / 98 (5.10%)	0 / 152 (0.00%)
occurrences (all)	7	5	0
Fever >39°C but ≤40°C Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	2 / 86 (2.33%)	0 / 98 (0.00%)	0 / 152 (0.00%)
occurrences (all)	2	0	0
Decreased appetite Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	15 / 87 (17.24%)	25 / 98 (25.51%)	0 / 152 (0.00%)
occurrences (all)	15	25	0
Irritability Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	30 / 87 (34.48%)	34 / 100 (34.00%)	0 / 152 (0.00%)
occurrences (all)	30	34	0
Increased sleep Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	8 / 86 (9.30%)	10 / 99 (10.10%)	0 / 152 (0.00%)
occurrences (all)	8	10	0
Decreased sleep Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[12]	16 / 87 (18.39%)	20 / 98 (20.41%)	0 / 152 (0.00%)
occurrences (all)	16	20	0
Fever ≥38°C but ≤39°C Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	4 / 78 (5.13%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	4	0	0
Fever >39°C but ≤40°C Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	1 / 79 (1.27%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	1	0	0
Decreased appetite Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	14 / 80 (17.50%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	14	0	0
Irritability Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	20 / 81 (24.69%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	20	0	0
Increased sleep Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	2 / 78 (2.56%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	2	0	0
Decreased sleep Dose 3 (Infant Series)			
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[18]	12 / 80 (15.00%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	12	0	0
Induration (Mild) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	16 / 78 (20.51%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	16	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	2
Allergy to arthropod sting			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 90 (6.67%)	8 / 112 (7.14%)	1 / 152 (0.66%)
occurrences (all)	6	9	1
Dyspepsia			
subjects affected / exposed	2 / 90 (2.22%)	2 / 112 (1.79%)	1 / 152 (0.66%)
occurrences (all)	2	2	1
Stomatitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Teething			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	1	0	0
Vomiting			

subjects affected / exposed	1 / 90 (1.11%)	1 / 112 (0.89%)	1 / 152 (0.66%)
occurrences (all)	1	1	1
Constipation			
subjects affected / exposed	0 / 90 (0.00%)	2 / 112 (1.79%)	0 / 152 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	2	0	0
Asthma			
subjects affected / exposed	1 / 90 (1.11%)	2 / 112 (1.79%)	1 / 152 (0.66%)
occurrences (all)	1	2	1
Cough			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	2 / 90 (2.22%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	2	1	0
Dermatitis diaper			
subjects affected / exposed	2 / 90 (2.22%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	2	1	0
Rash			
subjects affected / exposed	1 / 90 (1.11%)	1 / 112 (0.89%)	1 / 152 (0.66%)
occurrences (all)	1	1	1
Heat rash			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	2 / 152 (1.32%)
occurrences (all)	0	0	2
Dermatitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Swelling face			

subjects affected / exposed	0 / 90 (0.00%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	0	0	1
Tenderness (Any) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	13 / 86 (15.12%)	36 / 108 (33.33%)	63 / 149 (42.28%)
occurrences (all)	13	36	63
Tenderness (Significant) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	1 / 86 (1.16%)	0 / 108 (0.00%)	6 / 147 (4.08%)
occurrences (all)	1	0	6
Induration (Any) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	31 / 86 (36.05%)	49 / 110 (44.55%)	55 / 149 (36.91%)
occurrences (all)	31	49	55
Induration (Mild) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	28 / 86 (32.56%)	40 / 109 (36.70%)	42 / 149 (28.19%)
occurrences (all)	28	40	42
Induration (Moderate) Dose 1(Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	10 / 86 (11.63%)	27 / 109 (24.77%)	30 / 148 (20.27%)
occurrences (all)	10	27	30
Erythema (Any) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[25]	42 / 86 (48.84%)	77 / 110 (70.00%)	74 / 148 (50.00%)
occurrences (all)	42	77	74
Erythema (Moderate) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	14 / 86 (16.28%)	42 / 110 (38.18%)	38 / 148 (25.68%)
occurrences (all)	14	42	38
Tenderness (Any) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	13 / 86 (15.12%)	45 / 103 (43.69%)	0 / 152 (0.00%)
occurrences (all)	13	45	0
Tenderness (Significant) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	3 / 86 (3.49%)	4 / 98 (4.08%)	0 / 152 (0.00%)
occurrences (all)	3	4	0
Induration (Any) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	28 / 87 (32.18%)	43 / 105 (40.95%)	0 / 152 (0.00%)
occurrences (all)	28	43	0
Induration (Mild) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	25 / 87 (28.74%)	38 / 105 (36.19%)	0 / 152 (0.00%)
occurrences (all)	25	38	0
Induration (Moderate) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[31]	12 / 86 (13.95%)	12 / 99 (12.12%)	0 / 152 (0.00%)
occurrences (all)	12	12	0
Erythema (Any) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	40 / 87 (45.98%)	58 / 106 (54.72%)	0 / 152 (0.00%)
occurrences (all)	40	58	0
Erythema (Mild) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	35 / 87 (40.23%)	46 / 103 (44.66%)	0 / 152 (0.00%)
occurrences (all)	35	46	0
Erythema (Moderate) Dose 2 (Infant Series)	Additional description: Dose 2: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	8 / 86 (9.30%)	26 / 102 (25.49%)	0 / 152 (0.00%)
occurrences (all)	8	26	0
Tenderness (Any) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	12 / 79 (15.19%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	12	0	0
Tenderness (Significant) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	5 / 78 (6.41%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	5	0	0
Induration (Any) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[37]	20 / 80 (25.00%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	20	0	0
Induration (moderate) Dose 3 (infant Series).	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	9 / 80 (11.25%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	9	0	0
Erythema (Any) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[39]	31 / 82 (37.80%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	31	0	0
Erythema (Mild) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	25 / 80 (31.25%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	25	0	0
Erythema (Moderate) Dose 3 (Infant Series)	Additional description: Dose 3: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[41]	10 / 80 (12.50%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	10	0	0
Erythema (Mild) Dose 1 (Infant Series)	Additional description: Dose 1: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[42]	36 / 86 (41.86%)	61 / 110 (55.45%)	55 / 147 (37.41%)
occurrences (all)	36	61	55
Infections and infestations			
Pharyngitis			
subjects affected / exposed	12 / 90 (13.33%)	13 / 112 (11.61%)	5 / 152 (3.29%)
occurrences (all)	12	13	5

Nasopharyngitis			
subjects affected / exposed	11 / 90 (12.22%)	12 / 112 (10.71%)	5 / 152 (3.29%)
occurrences (all)	11	14	5
Upper respiratory tract infection			
subjects affected / exposed	8 / 90 (8.89%)	16 / 112 (14.29%)	4 / 152 (2.63%)
occurrences (all)	8	19	5
Bronchitis			
subjects affected / exposed	6 / 90 (6.67%)	9 / 112 (8.04%)	1 / 152 (0.66%)
occurrences (all)	6	9	1
Respiratory tract infection			
subjects affected / exposed	6 / 90 (6.67%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	6	0	1
Rhinitis			
subjects affected / exposed	6 / 90 (6.67%)	9 / 112 (8.04%)	4 / 152 (2.63%)
occurrences (all)	6	10	4
Exanthema subitum			
subjects affected / exposed	4 / 90 (4.44%)	2 / 112 (1.79%)	0 / 152 (0.00%)
occurrences (all)	4	2	0
Viral infection			
subjects affected / exposed	4 / 90 (4.44%)	2 / 112 (1.79%)	0 / 152 (0.00%)
occurrences (all)	4	2	0
Otitis media			
subjects affected / exposed	1 / 90 (1.11%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	2	1	0
Acute tonsillitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	1	0	1
Ear infection			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	0 / 152 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 90 (1.11%)	4 / 112 (3.57%)	2 / 152 (1.32%)
occurrences (all)	1	4	2
Laryngitis			
subjects affected / exposed	0 / 90 (0.00%)	4 / 112 (3.57%)	1 / 152 (0.66%)
occurrences (all)	0	4	1

Pneumonia			
subjects affected / exposed	1 / 90 (1.11%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 112 (0.00%)	1 / 152 (0.66%)
occurrences (all)	1	0	1
Varicella			
subjects affected / exposed	0 / 90 (0.00%)	1 / 112 (0.89%)	0 / 152 (0.00%)
occurrences (all)	0	1	0

Notes:

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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported