Clinical trial results:
A Phase 3, Open-Label Trial, Evaluating the Safety, Tolerability, and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine in Healthy Children Previously Partially Immunized With Prevenar.

Summary

EudraCT number	2008-003631-21
Trial protocol	SE
Global end of trial date	23 June 2010

Results information

Result version number	v1
This version publication date	29 June 2016
First version publication date	29 July 2015

Trial information

Trial identification

Sponsor protocol code	6096A1-3012-EU

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00824655
WHO universal trial number (UTN)	-
Other trial identifiers	Alias ID: B1851011

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, 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	06 December 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 June 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the pneumococcal immune response induced by 13-valent pneumococcal conjugate vaccine (13vPnC) when measured 1 month after the infant dose of 13vPnC in Group 1.

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	26 March 2009
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	Sweden: 234
Worldwide total number of subjects	234
EEA total number of subjects	234

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)	234
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 234 subjects were enrolled from Sweden. The study started on 26 March 2009 and completed on 6 December 2010. Group 1 (13vPnC/13vPnC) subjects received 1 dose of Prevenar at least 42 days prior to study enrollment. Group 2 (13vPnC) subjects received 2 doses of Prevenar with the last dose at least 140 days prior to study enrollment.

Period 1

Period 1 title	Overall trial (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/13vPnC

Arm description:

Subjects received 13vPnC at 5 months (Infant dose) and at 12 months (Toddler 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:

Subjects received single dose of 0.5 milliliter (mL) 13vPnC intramuscularly (IM) at 5 months (Infant dose) at 12 months (Toddler dose).

Arm title	13vPnC

Arm description:

Subjects received 13vPnC at 12 months (Toddler dose) of age.

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

Dosage and administration details:

Subjects received single dose of 0.5 mL 13vPnC IM at 12 months (Toddler dose).

Number of subjects in period 1	13vPnC/13vPnC	13vPnC
Started	118	116
Vaccinated infant dose	118	0 [1]
Vaccinated after infant dose	118	0 [2]
Vaccinated toddler dose	118	116
Completed	116	116
Not completed	2	0
Adverse Event	1	-
Parent/legal guardian request	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: Subjects of 13vPnC reporting group were not administered with toddler dose.

[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: Subjects of 13vPnC reporting group were not administered with toddler dose.

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC/13vPnC
Reporting group description:	
Subjects received 13vPnC at 5 months (Infant dose) and at 12 months (Toddler dose).	
Reporting group title	13vPnC
Reporting group description:	
Subjects received 13vPnC at 12 months (Toddler dose) of age.	

Reporting group values	13vPnC/13vPnC	13vPnC	Total
Number of subjects	118	116	234
Age categorical Units: Subjects			
Age continuous Units: months			
arithmetic mean	5.1	11.9	
standard deviation	± 0.37	± 0.52	-
Gender categorical Units: Subjects			
Female	50	60	110
Male	68	56	124

End points

End points reporting groups

Reporting group title	13vPnC/13vPnC
Reporting group description:	
Subjects received 13vPnC at 5 months (Infant dose) and at 12 months (Toddler dose).	
Reporting group title	13vPnC
Reporting group description:	
Subjects received 13vPnC at 12 months (Toddler dose) of age.	

Primary: Geometric Mean Concentration (GMC) of Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibodies 1 Month After the Toddler Dose

End point title	Geometric Mean Concentration (GMC) of Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibodies 1 Month After the Toddler Dose[1]

End point description:

Antibody geometric mean concentration (GMC) as measured by microgram (mcg) per 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) were presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) confidence intervals (CI) were evaluated. GMCs were calculated using all Subjects with available data for the specified blood draw. Evaluable Toddler Immunogenicity Population: eligible subjects who received study vaccine at the expected dose(s), blood drawn within specified timeframes, at least 1 valid and determinate assay result for proposed analysis, and no major protocol violations.

End point type	Primary

End point timeframe:

One month after the toddler dose (13 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: Only descriptive data was planned to be reported for this endpoint.

End point values	13vPnC/13vPnC	13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	115		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common Serotype 4	5.27 (4.43 to 6.26)	5.06 (4.22 to 6.06)		
Common Serotype 6B	9.63 (8.01 to 11.57)	8.75 (6.76 to 11.32)		
Common Serotype 9V	3.5 (3.01 to 4.07)	3.33 (2.88 to 3.84)		
Common Serotype 14	9.22 (7.66 to 11.09)	9.3 (7.9 to 10.95)		
Common Serotype 18C	2.93 (2.5 to 3.44)	3.87 (3.3 to 4.53)		
Common Serotype 19F	7.7 (6.12 to 9.69)	8.31 (6.39 to 10.81)		
Common Serotype 23F	3.27 (2.68 to 3.99)	4.4 (3.7 to 5.22)		
Additional Serotype 1	14.65 (12.5 to 17.17)	1.58 (1.3 to 1.93)		

Additional Serotype 3	1.85 (1.59 to 2.15)	1.34 (1.13 to 1.58)		
Additional Serotype 5	7.02 (5.98 to 8.25)	1.44 (1.21 to 1.72)		
Additional Serotype 6A	6.14 (5.08 to 7.43)	2.48 (1.89 to 3.26)		
Additional Serotype 7F	5.86 (5.11 to 6.72)	3.55 (3.09 to 4.08)		
Additional Serotype 19A	7.25 (6.14 to 8.57)	13.16 (11.26 to 15.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a Serotype-specific IgG Antibody Greater Than or Equal To (≥) 0.35 Mcg/mL, 1 Month After the Infant Dose

End point title	Percentage of Subjects Achieving a Serotype-specific IgG Antibody Greater Than or Equal To (≥) 0.35 Mcg/mL, 1 Month After the Infant Dose[2]

End point description:

Percentage of Subjects achieving predefined antibody threshold ≥0.35 mcg/mL along with the corresponding 95% CI for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Exact 2-sided CI based on the observed proportion of subjects. Evaluable Infant Immunogenicity Population: eligible subjects who received study vaccine at the expected dose(s), blood drawn within specified timeframes, at least 1 valid and determinate assay result for proposed analysis, and no major protocol violations.

End point type	Secondary

End point timeframe:

1 Month after the infant series (6 months of age)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The endpoint was planned to be assessed for subjects who received infant dose.

End point values	13vPnC/13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Common Serotype 4	99.1 (95.3 to 100)			
Common Serotype 6B	53 (43.5 to 62.4)			
Common Serotype 9V	99.1 (95.3 to 100)			
Common Serotype 14	96.5 (91.3 to 99)			
Common Serotype 18C	95.7 (90.1 to 98.6)			
Common Serotype 19F	92.2 (85.7 to 96.4)			
Common Serotype 23F	62.6 (53.1 to 71.5)			

Additional Serotype 1	80.9 (72.5 to 87.6)			
Additional Serotype 3	100 (96.8 to 100)			
Additional Serotype 5	83.5 (75.4 to 89.7)			
Additional Serotype 6A	36.8 (28 to 46.4)			
Additional Serotype 7F	93 (86.8 to 96.9)			
Additional Serotype 19A	87.8 (80.4 to 93.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serotype-Specific Pneumococcal IgG Antibodies Measured 1 Month After the Infant Dose

End point title	GMC of Serotype-Specific Pneumococcal IgG Antibodies Measured 1 Month After the Infant Dose[3]

End point description:

Antibody GMC 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) presented. GMC (13vPnC) and corresponding 2-sided 95% confidence intervals (CI) were evaluated. GMCs calculated using all Subjects with available data for the specified blood draw.
Evaluable Infant Immunogenicity Population.

End point type	Secondary

End point timeframe:

One Month after the infant series (6 months of age)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for subjects who received infant dose.

End point values	13vPnC/13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common Serotype 4	2.9 (2.48 to 3.4)			
Common Serotype 6B	0.4 (0.32 to 0.5)			
Common Serotype 9V	1.73 (1.5 to 1.99)			
Common Serotype 14	4.7 (3.72 to 5.92)			
Common Serotype 18C	1.56 (1.29 to 1.89)			
Common Serotype 19F	3.01 (2.34 to 3.88)			
Common Serotype 23F	0.57 (0.46 to 0.7)			

Additional Serotype 1	0.89 (0.73 to 1.08)			
Additional Serotype 3	1.88 (1.65 to 2.14)			
Additional Serotype 5	0.72 (0.62 to 0.84)			
Additional Serotype 6A	0.28 (0.23 to 0.34)			
Additional Serotype 7F	1.78 (1.48 to 2.15)			
Additional Serotype 19A	0.85 (0.73 to 0.99)			

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serotype-Specific Pneumococcal IgG Antibodies Measured Before the Toddler Dose

End point title	GMC of Serotype-Specific Pneumococcal IgG Antibodies Measured Before the Toddler Dose

End point description:

Antibody GMC 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) presented. GMC (13vPnC) and corresponding 2-sided 95% CIs evaluated. GMCs calculated using all subjects with available data for the specified blood draw. Evaluable Toddler Immunogenicity Population.

End point type	Secondary

End point timeframe:

Twelve months of age (prior to toddler dose)

End point values	13vPnC/13vPnC	13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	115		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common Serotype 4	0.66 (0.57 to 0.77)	0.62 (0.53 to 0.72)		
Common Serotype 6B	0.83 (0.67 to 1.02)	0.65 (0.51 to 0.82)		
Common Serotype 9V	0.74 (0.65 to 0.85)	0.7 (0.6 to 0.82)		
Common Serotype 14	1.99 (1.63 to 2.42)	2.23 (1.85 to 2.69)		
Common Serotype 18C	0.35 (0.3 to 0.41)	0.44 (0.38 to 0.51)		
Common Serotype 19F	0.85 (0.7 to 1.03)	0.81 (0.66 to 1)		
Common Serotype 23F	0.33 (0.27 to 0.39)	0.41 (0.34 to 0.49)		
Additional Serotype 1	0.46 (0.4 to 0.53)	0.01 (0.01 to 0.02)		

Additional Serotype 3	0.4 (0.34 to 0.47)	0.05 (0.04 to 0.07)		
Additional Serotype 5	1.18 (1.02 to 1.36)	0.33 (0.26 to 0.42)		
Additional Serotype 6A	0.71 (0.6 to 0.85)	0.24 (0.19 to 0.31)		
Additional Serotype 7F	1.08 (0.95 to 1.23)	0.02 (0.02 to 0.02)		
Additional Serotype 19A	1.06 (0.88 to 1.28)	1.55 (1.32 to 1.81)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of subjects Reporting Pre-specified Local Reactions: Infant Series Dose 1 (5 Months of Age)

End point title	Percentage of subjects Reporting Pre-specified Local Reactions: Infant Series Dose 1 (5 Months of Age)[4]

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 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 have been represented in more than 1 category. Safety Population: all subjects who received at least 1 dose of the study vaccine; n = number of subjects reporting yes for at least 1 day or no for all days for the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Day 1 through Day 7 after vaccination

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for subjects who received infant dose.

End point values	13vPnC/13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: Percentage of Subjects				
number (not applicable)				
Tenderness: Any (n=108)	36.1			
Tenderness: Significant (n=99)	3			
Swelling: Any (n=104)	33.7			
Swelling: Mild (n=104)	31.7			
Swelling: Moderate (n=101)	9.9			
Swelling: Severe (n=99)	0			
Redness: Any (n=107)	40.2			
Redness: Mild (n=107)	36.4			
Redness: Moderate (n=99)	4			
Redness: Severe (n=99)	0			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Local Reactions Within 7 Days of the Toddler Dose (12 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Local Reactions Within 7 Days of the Toddler Dose (12 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 or redness present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Subjects may have been represented in more than 1 category. Safety Population; n = number of subjects reporting yes for at least 1 day or no for all days for the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Day 1 through Day 7 after vaccination

End point values	13vPnC/13vPnC	13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	115		
Units: percentage of subjects				
number (not applicable)				
Tenderness: Any (n=104,110)	59.6	52.7		
Tenderness: Significant (n=96,103)	5.2	7.8		
Swelling: Any (n=104,110)	53.8	54.5		
Swelling: Mild (n=104,109)	50	52.3		
Swelling: Moderate (n=100,105)	24	29.5		
Swelling: Severe (n=95,101)	0	0		
Redness: Any (n=104,113)	62.5	59.3		
Redness: Mild (n=103,113)	52.4	51.3		
Redness: Moderate (n=98,106)	20.4	26.4		
Redness: Severe (n=95,101)	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Pre-specified Systemic Events Within 7 Days of the Infant Dose (5 Months of Age)

End point title	Percentage of Subjects Reporting Pre-specified Systemic Events Within 7 Days of the Infant Dose (5 Months of Age)[5]

End point description:

Systemic events (any fever ≥ 38 degrees Celsius [C], decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may have been represented in more than 1 category. Safety Population; n = number of subjects reporting yes for at least 1 day or no for all days for the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Day 1 through 7 after vaccination

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for subjects who received infant dose.

End point values	13vPnC/13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	117			
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 degrees C but ≤39 degrees C (n=103)	26.2			
Fever >39 degrees C but ≤40 degrees C (n=99)	2			
Fever >40 degrees C (n=99)	0			
Decreased appetite (n=107)	36.4			
Irritability (n=114)	80.7			
Increased sleep (n=106)	50.9			
Decreased sleep (n=112)	39.3			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of subjects Reporting Pre-specified Systemic Events Within 7 Days of the Toddler Dose (12 Months of Age)

End point title	Percentage of subjects Reporting Pre-specified Systemic Events Within 7 Days of the Toddler Dose (12 Months of Age)

End point description:

Systemic events (any fever ≥ 38 degrees C, decreased appetite, irritability, increased sleep, and decreased sleep) were reported using an electronic diary. Subjects may have been represented in more than 1 category. Safety Population; n = number of subjects reporting yes for at least 1 day or no for all days for the specific characteristic.

End point type	Other pre-specified

End point timeframe:

Day 1 through 7 after vaccination

End point values	13vPnC/13vPnC	13vPnC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	114		
Units: percentage of subjects				
number (not applicable)				
Fever ≥38 degrees C but ≤39 degrees C (n=99,105)	31.3	32.4		
Fever >39 degrees C but ≤40 degrees C (n=96,102)	5.2	3.9		

Fever >40 degrees C (n=95,101)	0	0		
Decreased appetite (n=103,109)	46.6	44		
Irritability (n=111,113)	82	76.1		
Increased sleep (n=101,108)	49.5	38.9		
Decreased sleep (n=105,106)	36.2	33		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs: Recorded from signing of informed consent form to completion of study(28-42 days post 13vPnC). Subjects recorded prespecified AEs in electronic diary:local reactions; systemic events (Day 1 - Day 7 post 13vPnC)

Adverse event reporting additional description:

The same event may appear as both an adverse event (AE) and a serious adverse event. However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another subject, or one subject may have experienced both a serious and non serious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC/13vPnC Infant series

Reporting group description:

13vPnC 0.5 mL dose administered IM at 5 months of age (infant dose)

Reporting group title	13vPnC/13vPnC After Infant series

Reporting group description:

13vPnC 0.5 mL dose administered IM at 5 months of age (infant dose); assessment 1 month after the infant series (6 months of age).

Reporting group title	13vPnC/13vPnC Toddler dose

Reporting group description:

13vPnC 0.5 mL dose administered IM at 5 months (infant dose) and 12 months of age (toddler dose).

Reporting group title	13vPnC Toddler dose

Reporting group description:

13vPnC 0.5 mL dose administered IM at 12 months of age (toddler dose).

Serious adverse events	13vPnC/13vPnC Infant series	13vPnC/13vPnC After Infant series	13vPnC/13vPnC Toddler dose
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 118 (0.85%)	4 / 118 (3.39%)	1 / 116 (0.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 118 (0.00%)	1 / 118 (0.85%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 118 (0.00%)	1 / 118 (0.85%)	0 / 116 (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 / 118 (0.00%)	0 / 118 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	1 / 116 (0.86%)
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 / 118 (0.00%)	4 / 118 (3.39%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	1 / 116 (0.86%)
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	13vPnC Toddler dose		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 116 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Foreign body			

subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	13vPnC/13vPnC Infant series	13vPnC/13vPnC After Infant series	13vPnC/13vPnC Toddler dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	107 / 118 (90.68%)	4 / 118 (3.39%)	98 / 116 (84.48%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Crying			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	4 / 116 (3.45%)
occurrences (all)	1	0	4
Injection site swelling			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Fever ≥38 degree C but ≤39 degree C (Infant Dose 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[1]	27 / 103 (26.21%)	0 / 118 (0.00%)	31 / 99 (31.31%)
occurrences (all)	27	0	31
Decreased appetite (Infant Dose 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]	39 / 107 (36.45%)	0 / 118 (0.00%)	48 / 103 (46.60%)
occurrences (all)	39	0	48
Irritability			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Increased sleep (Infant Dose 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]	54 / 106 (50.94%)	0 / 118 (0.00%)	50 / 101 (49.50%)
occurrences (all)	54	0	50
Decreased sleep (Infant Dose 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]	44 / 112 (39.29%)	0 / 118 (0.00%)	38 / 105 (36.19%)
occurrences (all)	44	0	38
Irritability (Systemic Event) Infant Dose 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]	92 / 114 (80.70%)	0 / 118 (0.00%)	91 / 111 (81.98%)
occurrences (all)	92	0	91
Fever >39 degree C but ≤40 degree C (Infant Dose 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[6]	2 / 99 (2.02%)	0 / 118 (0.00%)	5 / 96 (5.21%)
occurrences (all)	2	0	5
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	1 / 118 (0.85%)	1 / 118 (0.85%)	2 / 116 (1.72%)
occurrences (all)	1	1	2
Vomiting			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	5 / 116 (4.31%)
occurrences (all)	1	0	5
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 118 (0.00%)	1 / 118 (0.85%)	0 / 116 (0.00%)
occurrences (all)	0	1	0
Teething			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	1 / 116 (0.86%)
occurrences (all)	1	1	1
Obstructive airways disorder			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	1 / 118 (0.85%)	1 / 118 (0.85%)	0 / 116 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Erythema			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Tenderness (Any) Infant Dose 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[7] occurrences (all)	39 / 108 (36.11%) 39	0 / 118 (0.00%) 0	62 / 104 (59.62%) 62
Tenderness (Significant) Infant Dose 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[8] occurrences (all)	3 / 99 (3.03%) 3	0 / 118 (0.00%) 0	5 / 96 (5.21%) 5
Swelling (Any) Infant Dose 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[9] occurrences (all)	35 / 104 (33.65%) 35	0 / 118 (0.00%) 0	56 / 104 (53.85%) 56
Swelling (Mild) Infant Dose 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[10] occurrences (all)	33 / 104 (31.73%) 33	0 / 118 (0.00%) 0	52 / 104 (50.00%) 52
Swelling (Moderate) Infant Dose 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[11] occurrences (all)	10 / 101 (9.90%) 10	0 / 118 (0.00%) 0	24 / 100 (24.00%) 24
Redness (Any) Infant Dose 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[12]	43 / 107 (40.19%)	0 / 118 (0.00%)	65 / 104 (62.50%)
occurrences (all)	43	0	65
Redness (Mild) Infant Dose 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[13]	39 / 107 (36.45%)	0 / 118 (0.00%)	54 / 103 (52.43%)
occurrences (all)	39	0	54
Redness (Moderate) Infant Dose 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[14]	4 / 99 (4.04%)	0 / 118 (0.00%)	20 / 98 (20.41%)
occurrences (all)	4	0	20
Musculoskeletal and connective tissue disorders			
Lower extremity mass			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 118 (4.24%)	0 / 118 (0.00%)	8 / 116 (6.90%)
occurrences (all)	5	0	9
Exanthema subitum			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	3 / 116 (2.59%)
occurrences (all)	1	0	3
Pharyngitis streptococcal			
subjects affected / exposed	1 / 118 (0.85%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Mastitis			
subjects affected / exposed	0 / 118 (0.00%)	1 / 118 (0.85%)	0 / 116 (0.00%)
occurrences (all)	0	1	0
Ear infection			

subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Otitis media			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Varicella			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Bronchitis			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 118 (0.00%)	0 / 118 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 118 (0.00%)	1 / 118 (0.85%)	0 / 116 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	13vPnC Toddler dose		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	98 / 116 (84.48%)		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 116 (1.72%)		
occurrences (all)	2		
Foreign body			

subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Skin laceration			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Nervous system disorders			
Crying			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 116 (3.45%)		
occurrences (all)	6		
Injection site swelling			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
Fever ≥38 degree C but ≤39 degree C (Infant Dose 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[1]	34 / 105 (32.38%)		
occurrences (all)	34		
Decreased appetite (Infant Dose 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]	48 / 109 (44.04%)		
occurrences (all)	48		
Irritability			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Increased sleep (Infant Dose 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)	42 / 108 (38.89%) 42		
Decreased sleep (Infant Dose 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)	35 / 106 (33.02%) 35		
Irritability (Systemic Event) Infant Dose 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)	86 / 113 (76.11%) 86		
Fever >39 degree C but ≤40 degree C (Infant Dose 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[6] occurrences (all)	4 / 102 (3.92%) 4		
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Teething			

subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
Obstructive airways disorder			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
Rash macular			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Tenderness (Any) Infant Dose 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[7]	58 / 110 (52.73%)		
occurrences (all)	58		
Tenderness (Significant) Infant Dose 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[8]	8 / 103 (7.77%)		
occurrences (all)	8		
Swelling (Any) Infant Dose 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[9]	60 / 110 (54.55%)		
occurrences (all)	60		
Swelling (Mild) Infant Dose 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[10]	57 / 109 (52.29%)		
occurrences (all)	57		
Swelling (Moderate) Infant Dose 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[11]	31 / 105 (29.52%)		
occurrences (all)	31		
Redness (Any) Infant Dose 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[12]	67 / 113 (59.29%)		
occurrences (all)	67		
Redness (Mild) Infant Dose 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[13]	58 / 113 (51.33%)		
occurrences (all)	58		
Redness (Moderate) Infant Dose 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[14] occurrences (all)	28 / 106 (26.42%) 28		
Musculoskeletal and connective tissue disorders Lower extremity mass subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	7 / 116 (6.03%) 9		
Exanthema subitum subjects affected / exposed occurrences (all)	2 / 116 (1.72%) 2		
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Mastitis subjects affected / exposed occurrences (all)	0 / 116 (0.00%) 0		
Ear infection subjects affected / exposed occurrences (all)	3 / 116 (2.59%) 4		
Otitis media subjects affected / exposed occurrences (all)	2 / 116 (1.72%) 3		
Varicella subjects affected / exposed occurrences (all)	1 / 116 (0.86%) 1		
Upper respiratory tract infection			

subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Croup infectious			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	1 / 116 (0.86%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	0 / 116 (0.00%)		
occurrences (all)	0		

Notes:

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

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

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

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

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

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

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

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

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

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