Clinical trial results:
A Phase 3, Open Label Trial Evaluating the Safety,Tolerability and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine in Healthy Children Aged 15 Months to 17 Years in the United States

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

Summary

EudraCT number	2009-017304-88
Trial protocol	Outside EU/EEA
Global end of trial date	10 August 2010

Results information

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

Trial information

Trial identification

Sponsor protocol code	6096A1-3011

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00761631
WHO universal trial number (UTN)	-
Other trial identifiers	Alias ID: B1851010

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	07 March 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 August 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1-To assess the pneumococcal immune responses induced by 13-valent pneumococcal conjugate vaccine (13vPnC) when measured 1 month after the last scheduled dose of 13vPnC in each of 4 age groups.
2- To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and AEs. This objective is applicable to all 4 groups and both cohorts.

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	18 November 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1200
Worldwide total number of subjects	1200
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	302
Children (2-11 years)	671
Adolescents (12-17 years)	227
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:

Subjects were stratified by age group. Group 1 included subjects aged greater than (>) 15 months to less than (<) 2 years. Group 2 included subjects aged greater than or equal to (>=) 2 to <5 years. Group 3 included subjects aged >=5 to <10 years. Group 4 included subjects aged >=10 to <18 years.

Period 1

Period 1 title	Overall Study (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 Group 1 (Cohort 1)

Arm description:

13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7-valent pneumococcal conjugate vaccine (7vPnC). Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

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 0.5 milliliter (mL) dose of 13vPnC at baseline and anytime from Day 56 to Day 70 for a total of 2 doses.

Arm title	13vPnC Group 2 (Cohort 1)

Arm description:

13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

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 13vPnC 0.5 mL dose at baseline.

Arm title	13vPnC Group 1 (Cohort 2)

Arm description:

13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

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 0.5 mL dose of 13vPnC dose at baseline and anytime from Day 56 to Day 70 for a total of 2 doses.

Arm title	13vPnC Group 2 (Cohort 2)

Arm description:

13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

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 0.5 mL dose of 13vPnC at baseline.

Arm title	13vPnC Group 3

Arm description:

13vPnC administered at baseline. Subjects must have previously received at least 1 dose of 7vPnC.

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 0.5 mL dose of 13vPnC at baseline.

Arm title	13vPnC Group 4

Arm description:

13vPnC administered at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine.

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 0.5 mL dose of 13vPnC at baseline.

Number of subjects in period 1	13vPnC Group 1 (Cohort 1)	13vPnC Group 2 (Cohort 1)	13vPnC Group 1 (Cohort 2)
Started	126	181	176
Vaccinated Dose 1	124	179	175
Vaccinated Dose 2	112	0 [1]	165
Completed	111	174	160
Not completed	15	7	16
Physician decision	1	-	-
Failed to return	1	-	1
Parent/legal guardian request	8	3	8
Unspecified	-	-	-
Lost to follow-up	2	4	7
Randomized, not treated	1	-	-
Protocol deviation	2	-	-

Number of subjects in period 1	13vPnC Group 2 (Cohort 2)	13vPnC Group 3	13vPnC Group 4
Started	119	299	299
Vaccinated Dose 1	118	294	298
Vaccinated Dose 2	0 [2]	0 [3]	0 [4]
Completed	116	277	294
Not completed	3	22	5
Physician decision	-	-	-
Failed to return	1	5	2
Parent/legal guardian request	-	5	-
Unspecified	-	1	1
Lost to follow-up	1	6	1
Randomized, not treated	-	-	-
Protocol deviation	1	5	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 in 13vPnC Group 2 were planned to receive only dose 1 of 13vPnC.

[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 in 13vPnC Group 2 were planned to receive only dose 1 of 13vPnC.

[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: Subjects in 13vPnC Group 3 were planned to receive only dose 1 of 13vPnC.

[4] - 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 in 13vPnC Group 4 were planned to receive only dose 1 of 13vPnC.

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC Group 1 (Cohort 1)
Reporting group description:	
13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7-valent pneumococcal conjugate vaccine (7vPnC). Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).	
Reporting group title	13vPnC Group 2 (Cohort 1)
Reporting group description:	
13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).	
Reporting group title	13vPnC Group 1 (Cohort 2)
Reporting group description:	
13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).	
Reporting group title	13vPnC Group 2 (Cohort 2)
Reporting group description:	
13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).	
Reporting group title	13vPnC Group 3
Reporting group description:	
13vPnC administered at baseline. Subjects must have previously received at least 1 dose of 7vPnC.	
Reporting group title	13vPnC Group 4
Reporting group description:	
13vPnC administered at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine.	

Reporting group values	13vPnC Group 1 (Cohort 1)	13vPnC Group 2 (Cohort 1)	13vPnC Group 1 (Cohort 2)
Number of subjects	126	181	176
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	126	0	176
Children (2-11 years)	0	181	0
Adolescents (12-17 years)	0	0	0
Gender categorical Units: Subjects			
Female	65	74	83
Male	61	107	93

Reporting group values	13vPnC Group 2 (Cohort 2)	13vPnC Group 3	13vPnC Group 4
Number of subjects	119	299	299
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	119	299	72
Adolescents (12-17 years)	0	0	227

Gender categorical Units: Subjects			
Female	65	155	136
Male	54	144	163

Reporting group values	Total		
Number of subjects	1200		
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	302		
Children (2-11 years)	671		
Adolescents (12-17 years)	227		
Gender categorical Units: Subjects			
Female	578		
Male	622		

End points

End points reporting groups

Reporting group title	13vPnC Group 1 (Cohort 1)
Reporting group description:	
13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7-valent pneumococcal conjugate vaccine (7vPnC). Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).	
Reporting group title	13vPnC Group 2 (Cohort 1)
Reporting group description:	
13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).	
Reporting group title	13vPnC Group 1 (Cohort 2)
Reporting group description:	
13vPnC administered at baseline and anytime from Day 56 to Day 70 for a total of 2 doses. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).	
Reporting group title	13vPnC Group 2 (Cohort 2)
Reporting group description:	
13vPnC administered at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).	
Reporting group title	13vPnC Group 3
Reporting group description:	
13vPnC administered at baseline. Subjects must have previously received at least 1 dose of 7vPnC.	
Reporting group title	13vPnC Group 4
Reporting group description:	
13vPnC administered at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine.	

Primary: Percentage of Subjects Achieving Predefined Serotype-specific Immunoglobulin G (IgG) Antibody Concentration Greater Than or Equal to (>=) 0.35 Micrograms Per Milliliter (Mcg/mL) Measured 1 Month After Vaccination in Group 1 and 2

End point title	Percentage of Subjects Achieving Predefined Serotype-specific Immunoglobulin G (IgG) Antibody Concentration Greater Than or Equal to (>=) 0.35 Micrograms Per Milliliter (Mcg/mL) Measured 1 Month After Vaccination in Group 1 and 2[1][2]
End point description:	
Percentage of subjects achieving world health organization (WHO) predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% 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) were presented. Exact 2-sided CI based on observed proportion of subjects. Evaluable Immunogenicity Population (EIP): all subjects who met all inclusion criteria, received all assigned doses of study vaccine, had at least 1 valid and determinate assay result from blood draw within 27-56 days after last scheduled vaccination for proposed analysis and no major protocol violations.	
End point type	Primary
End point timeframe:	
28 to 42 days after dose 2 for Group 1 and 28 to 42 days after dose 1 for Group 2	

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.

[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 reported for reporting group 13vPnC Group 1 (Cohort 1) and 13vPnC Group 2 (Cohort 1) only.

End point values	13vPnC Group 1 (Cohort 1)	13vPnC Group 2 (Cohort 1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	175		
Units: Percentage of subjects				
number (confidence interval 95%)				
Common serotypes - serotype 4	98.2 (93.5 to 99.8)	100 (97.9 to 100)		
Common serotypes - serotype 6B	100 (96.7 to 100)	100 (97.9 to 100)		
Common serotypes - serotype 9V	100 (96.7 to 100)	100 (97.9 to 100)		
Common serotypes - serotype 14	100 (96.7 to 100)	100 (97.9 to 100)		
Common serotypes - serotype 18C	100 (96.7 to 100)	100 (97.9 to 100)		
Common serotypes - serotype 19F	100 (96.7 to 100)	100 (97.9 to 100)		
Common serotypes - serotype 23F	99.1 (95 to 100)	100 (97.9 to 100)		
Additional serotypes - serotype 1	100 (96.7 to 100)	98.9 (95.9 to 99.9)		
Additional serotypes - serotype 3	94.5 (88.4 to 98)	92 (86.9 to 95.5)		
Additional serotypes - serotype 5	100 (96.7 to 100)	98.9 (95.9 to 99.9)		
Additional serotypes - serotype 6A	100 (96.7 to 100)	100 (97.9 to 100)		
Additional serotypes - serotype 7F	100 (96.7 to 100)	100 (97.9 to 100)		
Additional serotypes - serotype 19A	100 (96.7 to 100)	100 (97.9 to 100)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After Vaccination in Group 3

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After Vaccination in Group 3[3][4]

End point description:

Antibody GMC 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) were presented. GMC (13vPnC) and corresponding 2-sided 95% confidence intervals (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for after dose 1 blood draw. EIP: subjects who met all inclusion criteria, received all assigned doses of study vaccine;had at least 1 valid, determinate assay result from blood draw within 27-56 days after last scheduled vaccination for proposed analysis;no major protocol violations.

End point type	Primary

End point timeframe:

28 to 42 days after dose 1 for Group 3

Notes:

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

[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 reported for reporting group 13vPnC Group 3 only.

End point values	13vPnC Group 3			
Subject group type	Reporting group			
Number of subjects analysed	171[5]			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4	8.45 (7.24 to 9.87)			
Common serotypes - serotype 6B	53.56 (45.48 to 63.07)			
Common serotypes - serotype 9V	9.51 (8.38 to 10.78)			
Common serotypes - serotype 14	29.36 (24.78 to 34.78)			
Common serotypes - serotype 18C	8.23 (7.13 to 9.51)			
Common serotypes - serotype 19F	17.58 (14.95 to 20.67)			
Common serotypes - serotype 23F	11.26 (9.79 to 12.95)			
Additional serotypes - serotype 1	3.57 (3.05 to 4.18)			
Additional serotypes - serotype 3	2.38 (2.07 to 2.74)			
Additional serotypes - serotype 5	5.52 (4.82 to 6.32)			
Additional serotypes - serotype 6A	21.51 (18.15 to 25.51)			
Additional serotypes - serotype 7F	6.24 (5.49 to 7.08)			
Additional serotypes - serotype 19A	17.18 (15.01 to 19.67)			

Notes:

[5] - Subjects with determinate antibody concentration.

Statistical analyses

No statistical analyses for this end point

Primary: Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) 1 Month After Vaccination in Group 3 and 4

End point title	Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) 1 Month After Vaccination in Group 3 and 4[6]

End point description:

Serotype-specific OPA GMTs 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) were determined in the blood samples of all the subjects using a microcolony OPA (mcOPA)

assay. GMT (13vPnC) and corresponding 2-sided 95% CI were evaluated. GMs were calculated using all subjects with available data for after dose 1 blood draw. EIP: subjects who met all inclusion criteria, received all assigned doses of study vaccine;had at least 1 valid, determinate assay result from blood draw within 27-56 days after last scheduled vaccination for proposed analysis;no major protocol violations.

End point type	Primary

End point timeframe:

28 to 42 days after dose 1 for Group 3 and 4

Notes:

[6] - 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 reported for reporting group 13vPnC Group 3 and 13vPnC Group 4 only.

End point values	13vPnC Group 3	13vPnC Group 4		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	181		
Units: titer				
geometric mean (confidence interval 95%)				
Common serotypes - serotype 4	6912 (6101.2 to 7831.4)	4629 (4017.2 to 5334.3)		
Common serotypes - serotype 6B	14224 (12316.4 to 16427.3)	14996 (13164.1 to 17083.1)		
Common serotypes - serotype 9V	4485 (4001.1 to 5027.5)	4733 (4203.3 to 5328.4)		
Common serotypes - serotype 14	6894 (6028.3 to 7884)	4759 (4120.4 to 5497)		
Common serotypes - serotype 18C	6263 (5436.4 to 7215.1)	8815 (7738.2 to 10041)		
Common serotypes - serotype 19F	2280 (1949.4 to 2667.6)	1559 (1293.3 to 1878.9)		
Common serotypes - serotype 23F	3808 (3354.7 to 4322.6)	3245 (2818.8 to 3735.5)		
Additional serotypes - serotype 1	319 (271.2 to 376)	187 (160.4 to 218.6)		
Additional serotypes - serotype 3	114 (100.4 to 129.4)	202 (180.9 to 226.3)		
Additional serotypes - serotype 5	336 (270.3 to 417.6)	491 (426.3 to 565.3)		
Additional serotypes - serotype 6A	9928 (8457 to 11654.8)	7514 (6350.8 to 8890.7)		
Additional serotypes - serotype 7F	6584 (5829.4 to 7435.5)	10334 (9099 to 11736.8)		
Additional serotypes - serotype 19A	1276 (1131.7 to 1439)	1180 (1047.5 to 1329.4)		

Statistical analyses

Statistical analysis title	Serotype 4

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3

Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	GMT Ratio
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.24
upper limit	1.8

Notes:

[7] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 6B

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 3 v 13vPnC Group 4
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.15

Notes:

[8] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 9V

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	GMT Ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.12

Notes:

[9] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 14

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
Parameter estimate	GMT Ratio
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.19
upper limit	1.76

Notes:

[10] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 18C

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.86

Notes:

[11] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 19F

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
Parameter estimate	GMT Ratio
Point estimate	1.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	1.86

Notes:

[12] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 23F

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	GMT Ratio
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.42

Notes:

[13] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 1

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[14]
Parameter estimate	GMT Ratio
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.36
upper limit	2.13

Notes:

[14] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 3

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.67

Notes:

[15] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 5

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[16]
Parameter estimate	GMT Ratio
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.89

Notes:

[16] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 6A

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[17]
Parameter estimate	GMT Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	1.67

Notes:

[17] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 7F

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[18]
Parameter estimate	GMT Ratio
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.76

Notes:

[18] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Statistical analysis title	Serotype 19A

Statistical analysis description:

CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC Group 4 – 13vPnC Group 3).

Comparison groups	13vPnC Group 4 v 13vPnC Group 3
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[19]
Parameter estimate	GMT Ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.28

Notes:

[19] - Non-inferiority was to be concluded if the lower bound of the 2-sided 95% CI was greater than 0.5.

Primary: Comparison of Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After 13vPnC Vaccination in Group 3 Relative to Posttoddler Responses in Study 6096A1-3005 (NCT00444457)

End point title	Comparison of Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody Measured 1 Month After 13vPnC Vaccination in Group 3 Relative to Posttoddler Responses in Study 6096A1-3005 (NCT00444457)[20][21]

End point description:

End point type	Primary

End point timeframe:

28 to 42 days after dose 1

Notes:

[20] - 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.

[21] - 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 reported for reporting group 13vPnC Group 3 only.

End point values	13vPnC Group 3			
Subject group type	Reporting group			
Number of subjects analysed	0[22]			
Units: mcg/mL				
arithmetic mean (standard deviation)	()			

Notes:

[22] - Data not reported because analysis population includes subjects who were not enrolled in this study.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 1

End point title	Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 1

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). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Dose 1 Safety Population: all subjects who received the first dose of 13vPnC.'n'=number of subjects with known values for specified local reaction for each group respectively. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

From the day of dose 1 (Day 1) to Day 7 after dose 1

End point values	13vPnC Group 1 (Cohort 1)	13vPnC Group 2 (Cohort 1)	13vPnC Group 1 (Cohort 2)	13vPnC Group 2 (Cohort 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110[23]	158[24]	151[25]	102[26]
Units: Percentage of subjects				
number (not applicable)				
Tenderness Any (n=108,155, 148,102,265,283)	50.9	61.9	45.3	62.7
Tenderness Significant (n=92,141,133,92,221,242)	7.6	10.6	5.3	13
Swelling Any (n=97,144,142,90,226,233)	25.8	22.2	17.6	20
Swelling Mild (n=94,143,141,89,220,221)	21.3	20.3	14.2	13.5

Swelling Moderate (n=94,141,135,89,219,226)	9.6	5.7	7.4	11.2
Swelling Severe (n=90,138,131,88,211,214)	0	0	0	1.1
Redness Any (n=103,149,143,91,233,232)	39.8	34.9	18.9	36.3
Redness Mild (n=99,146,143,90,226,226)	31.3	31.5	16.8	31.1
Redness Moderate (n=94,142,135,89,218,221)	12.8	9.9	5.9	14.6
Redness Severe (n=90,138,131,88,212,213)	0	0	0.8	1.1

Notes:

[23] - Subjects with known values for any local reaction.

[24] - Subjects with known values for any local reaction.

[25] - Subjects with known values for any local reaction.

[26] - Subjects with known values for any local reaction.

End point values	13vPnC Group 3	13vPnC Group 4		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	270[27]	285[28]		
Units: Percentage of subjects				
number (not applicable)				
Tenderness Any (n=108,155, 148,102,265,283)	86.8	89		
Tenderness Significant (n=92,141,133,92,221,242)	19.5	43.8		
Swelling Any (n=97,144,142,90,226,233)	37.6	36.9		
Swelling Mild (n=94,143,141,89,220,221)	21.8	22.6		
Swelling Moderate (n=94,141,135,89,219,226)	21.9	21.2		
Swelling Severe (n=90,138,131,88,211,214)	3.3	1.9		
Redness Any (n=103,149,143,91,233,232)	42.9	30.2		
Redness Mild (n=99,146,143,90,226,226)	27.9	21.2		
Redness Moderate (n=94,142,135,89,218,221)	22	14		
Redness Severe (n=90,138,131,88,212,213)	3.3	1.9		

Notes:

[27] - Subjects with known values for any local reaction.

[28] - Subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 2

End point title	Percentage of Subjects Reporting Prespecified Local Reactions Within 7 Days of Dose 2[29]

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). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.5 to 7.0 cm); Severe (> 7.0 cm). Dose 2 Safety Population: all subjects who received 2 doses of 13vPnC. Here, 'n'=number of subjects with known values for specified local reaction for each group respectively. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

From the day of dose 2 (Day 1) to Day 7 of dose 2

Notes:

[29] - 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 reported for reporting group 13vPnC Group 1 (Cohort 1) and 13vPnC Group 2 (Cohort 1) only.

End point values	13vPnC Group 1 (Cohort 1)	13vPnC Group 1 (Cohort 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90[30]	131[31]		
Units: Percentage of subjects				
number (not applicable)				
Tenderness Any (n=87, 125)	57.5	55.2		
Tenderness Significant (n=68, 101)	8.8	9.9		
Swelling Any (n=73, 105)	23.3	17.1		
Swelling Mild (n=72, 104)	22.2	15.4		
Swelling Moderate (n=69, 102)	2.9	7.8		
Swelling Severe (n=68, 98)	0	0		
Redness Any (n=76, 110)	35.5	23.6		
Redness Mild (n=74, 108)	33.8	18.5		
Redness Moderate (n=70, 100)	7.1	6		
Redness Severe (n=68, 98)	0	0		

Notes:

[30] - Subjects with known values for any local reaction.

[31] - Subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 1

End point title	Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 1

End point description:

Systemic events (any fever >=38 degrees [deg] Celsius [C], decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]) were reported using an electronic diary. Dose 1 Safety Population: all subjects who received the first dose of 13vPnC. Here, 'n'=number of subjects with known values for specified systemic events for each group respectively. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

From the day of dose 1 (Day 1) to Day 7 of dose 1

End point values	13vPnC Group 1 (Cohort 1)	13vPnC Group 2 (Cohort 1)	13vPnC Group 1 (Cohort 2)	13vPnC Group 2 (Cohort 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112[32]	157[33]	165[34]	107[35]
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 to <=39 degC(n=92,138,137,90,212,214)	16.3	5.1	17.5	14.4
Fever >39 but <=40 degC(n=90,138,130,89,212,212)	4.4	0.7	4.6	3.4
Fever >40 degC (n=90,138,130,88,210,212)	0	0.7	0	1.1
Decreased appetite (n=99,149,146,94,227,223)	42.4	24.8	39.7	34
Irritability (n=108,151,156,102,234,234)	60.2	39.7	72.4	52
Increased sleep (n=98,145,146,97,226,229)	32.7	15.9	37	23.7
Decreased sleep (n=97,143,140,91,212,224)	22.7	14	32.1	18.7
Hives (urticaria) (n=90,139,131,88,213,214)	1.1	0.7	1.5	4.5

Notes:

[32] - Subjects with known values for any systemic events.

[33] - Subjects with known values for any systemic events.

[34] - Subjects with known values for any systemic events.

[35] - Subjects with known values for any systemic events.

End point values	13vPnC Group 3	13vPnC Group 4		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	250[36]	253[37]		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 to <=39 degC(n=92,138,137,90,212,214)	4.2	5.1		
Fever >39 but <=40 degC(n=90,138,130,89,212,212)	2.4	0.5		
Fever >40 degC (n=90,138,130,88,210,212)	0.5	0.5		
Decreased appetite (n=99,149,146,94,227,223)	22.9	22.9		
Irritability (n=108,151,156,102,234,234)	31.2	25.2		
Increased sleep (n=98,145,146,97,226,229)	21.2	26.6		
Decreased sleep (n=97,143,140,91,212,224)	5.7	18.8		
Hives (urticaria) (n=90,139,131,88,213,214)	1.9	1.4		

Notes:

[36] - Subjects with known values for any systemic events.

[37] - Subjects with known values for any systemic events.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 2

End point title	Percentage of Subjects Reporting Prespecified Systemic Events Within 7 Days of Dose 2[38]

End point description:

Systemic events (any fever >=38 deg C, decreased appetite, irritability, increased sleep, decreased sleep, and hives [urticaria]) were reported using an electronic diary. Subjects may have been represented in more than 1 category. Percentage of subjects = number of subjects reporting specified systemic event divided by number of subjects reporting yes for at least 1 day or no for all days. Dose 2 Safety Population: all subjects who received 2 doses of 13vPnC. Here, 'n'=number of subjects with known values for specified systemic events for each group respectively. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

From the day of dose 2 (Day 1) to Day 7 of dose 2

Notes:

[38] - 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 reported for reporting group 13vPnC Group 1 (Cohort 1) and 13vPnC Group 1 (Cohort 2) only.

End point values	13vPnC Group 1 (Cohort 1)	13vPnC Group 1 (Cohort 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91[39]	137[40]		
Units: Percentage of subjects				
number (not applicable)				
Fever >=38 but <=39 degC (n=70,101)	14.3	11.9		
Fever >39 but <=40 degC (n=68, 100)	4.4	2		
Fever >40 degC (n=68, 98)	0	1		
Decreased appetite (n=77, 113)	40.3	34.5		
Irritability (n=86, 126)	65.1	61.1		
Increased sleep (n=75, 109)	29.3	23.9		
Decreased sleep (n=77, 112)	28.6	26.8		
Hives (urticaria) (n=68, 98)	2.9	0		

Notes:

[39] - Subjects with known values for any systemic events.

[40] - Subjects with known values for any systemic events.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Group 1: Baseline up to Day 280; Group 2, 3 and 4: Baseline up to Day 210. Participants recorded pre-specified AEs in electronic diary:local reactions; systemic events (up to 7 days after each vaccine dose)

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included solicited AEs collected in the electronic diary (local and systemic reactions; systematic assessment) and unsolicited events collected on the case report form at each visit (nonsystematic assessment). Version was not captured, hence 0.0 is mentioned for dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC Group 1 (Cohort 1) Dose 1

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

Reporting group title	13vPnC Group 1 (Cohort 1) Dose 2

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly anytime from Day 56 to Day 70. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

Reporting group title	13vPnC Group 2 (Cohort 1) Dose 1

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled prior to protocol amendment to increase sample size (Cohort 1).

Reporting group title	13vPnC Group 1 (Cohort 2) Dose 1

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

Reporting group title	13vPnC Group 1 (Cohort 2) Dose 2

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly anytime from Day 56 to Day 70. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

Reporting group title	13vPnC Group 2 (Cohort 2) Dose 1

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received at least 3 doses of 7vPnC. Includes subjects enrolled after protocol amendment to increase sample size (Cohort 2).

Reporting group title	6-Month Follow-up 13vPnC Group 1 (Cohort 1 and 2)

Reporting group description:

6-month follow-up telephone contact for subjects in Group 1 (Cohort 1 and 2).

Reporting group title	6-Month Follow-up 13vPnC Group 2 (Cohort 1 and 2)

Reporting group description:

6-month follow-up telephone contact for subjects in Group 2 (Cohort 1 and 2).

Reporting group title	13vPnC Group 3

Reporting group description:

13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must have previously received

at least 1 dose of 7vPnC.

Reporting group title	6-Month Follow-up 13vPnC Group 3
Reporting group description:	
6-month follow-up telephone contact for subjects in Group 3.	
Reporting group title	13vPnC Group 4
Reporting group description:	
13vPnC (0.5mL dose) administered intramuscularly at baseline. Subjects must not have received 7vPnC or any other pneumococcal vaccine.	
Reporting group title	6-Month Follow-up 13vPnC Group 4
Reporting group description:	
6 -Month Follow-up Telephone Contact for subjects in Group 4.	

Serious adverse events	13vPnC Group 1 (Cohort 1) Dose 1	13vPnC Group 1 (Cohort 1) Dose 2	13vPnC Group 2 (Cohort 1) Dose 1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 124 (0.00%)	2 / 112 (1.79%)	1 / 179 (0.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Near drowning			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Wheezing			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (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
Bronchiolitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC Group 1 (Cohort 2) Dose 1	13vPnC Group 1 (Cohort 2) Dose 2	13vPnC Group 2 (Cohort 2) Dose 1
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 175 (0.57%)	4 / 165 (2.42%)	0 / 118 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Near drowning			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (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
Abdominal injury			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Wheezing			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (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
Status asthmaticus			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal infection			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (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
Appendicitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	6-Month Follow-up 13vPnC Group 1 (Cohort 1 and 2)	6-Month Follow-up 13vPnC Group 2 (Cohort 1 and 2)	13vPnC Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 299 (1.00%)	1 / 297 (0.34%)	1 / 294 (0.34%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Near drowning			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal injury			
subjects affected / exposed	1 / 299 (0.33%)	0 / 297 (0.00%)	0 / 294 (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 / 299 (0.33%)	0 / 297 (0.00%)	0 / 294 (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			
Vomiting			
subjects affected / exposed	1 / 299 (0.33%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Wheezing			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 299 (0.00%)	1 / 297 (0.34%)	0 / 294 (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
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	1 / 299 (0.33%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
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	6-Month Follow-up 13vPnC Group 3	13vPnC Group 4	6-Month Follow-up 13vPnC Group 4
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	1 / 298 (0.34%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Near drowning			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal injury			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Wheezing			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	1 / 298 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	13vPnC Group 1 (Cohort 1) Dose 1	13vPnC Group 1 (Cohort 1) Dose 2	13vPnC Group 2 (Cohort 1) Dose 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	88 / 124 (70.97%)	71 / 112 (63.39%)	112 / 179 (62.57%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 124 (4.03%)	3 / 112 (2.68%)	3 / 179 (1.68%)
occurrences (all)	5	3	3
Injection site pruritus			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Injection site pain			

subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Fever >=38 degrees C but <=39 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	15 / 92 (16.30%)	10 / 70 (14.29%)	7 / 138 (5.07%)
occurrences (all)	15	10	7
Fever >39 degrees C but <=40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e-diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	4 / 90 (4.44%)	3 / 68 (4.41%)	1 / 138 (0.72%)
occurrences (all)	4	3	1
Fever >40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 90 (0.00%)	0 / 68 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	0	1
Decreased appetite	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	42 / 99 (42.42%)	31 / 77 (40.26%)	37 / 149 (24.83%)
occurrences (all)	42	31	37
Irritability	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	65 / 108 (60.19%)	56 / 86 (65.12%)	60 / 151 (39.74%)
occurrences (all)	65	56	60
Increased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[6]	32 / 98 (32.65%)	22 / 75 (29.33%)	23 / 145 (15.86%)
occurrences (all)	32	22	23
Decreased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	22 / 97 (22.68%)	22 / 77 (28.57%)	20 / 143 (13.99%)
occurrences (all)	22	22	20
Hives (urticaria)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	1 / 90 (1.11%)	2 / 68 (2.94%)	1 / 139 (0.72%)
occurrences (all)	1	2	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal discomfort			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Penile adhesion			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 124 (4.03%)	0 / 112 (0.00%)	7 / 179 (3.91%)
occurrences (all)	5	0	7
Rhinorrhoea			

subjects affected / exposed	5 / 124 (4.03%)	2 / 112 (1.79%)	4 / 179 (2.23%)
occurrences (all)	6	2	4
Epistaxis			
subjects affected / exposed	2 / 124 (1.61%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	2	0	1
Nasal congestion			
subjects affected / exposed	1 / 124 (0.81%)	1 / 112 (0.89%)	1 / 179 (0.56%)
occurrences (all)	1	1	1
Pneumonitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	2	0	0
Wheezing			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	4 / 179 (2.23%)
occurrences (all)	0	0	4
Oropharyngeal pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Bronchospasm			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			

subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Asperger's disorder			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Excoriation			

subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Lower limb fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Head injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Traumatic brain injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Ulna fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Periorbital haematoma			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			

subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	1	0	1
Speech disorder developmental			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0

Somnolence			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Eustachian tube dysfunction			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	2 / 124 (1.61%)	4 / 112 (3.57%)	2 / 179 (1.12%)
occurrences (all)	2	4	2
Hypermetropia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	7 / 124 (5.65%)	1 / 112 (0.89%)	1 / 179 (0.56%)
occurrences (all)	7	1	1

Diarrhoea			
subjects affected / exposed	6 / 124 (4.84%)	1 / 112 (0.89%)	4 / 179 (2.23%)
occurrences (all)	6	1	4
Constipation			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	1 / 179 (0.56%)
occurrences (all)	0	1	1
Tongue coated			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	0	1	0
Duodenogastric reflux			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Uvulitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 124 (1.61%)	2 / 112 (1.79%)	2 / 179 (1.12%)
occurrences (all)	2	2	2
Dermatitis			
subjects affected / exposed	2 / 124 (1.61%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	2	0	0
Dermatitis contact			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Dermatitis diaper			
subjects affected / exposed	1 / 124 (0.81%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	1	1	0
Eczema			
subjects affected / exposed	1 / 124 (0.81%)	2 / 112 (1.79%)	0 / 179 (0.00%)
occurrences (all)	1	2	0
Skin disorder			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Acanthosis nigricans			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Tenderness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	55 / 108 (50.93%) 55	50 / 87 (57.47%) 50	96 / 155 (61.94%) 96
Tenderness (significant)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	7 / 92 (7.61%) 7	6 / 68 (8.82%) 6	15 / 141 (10.64%) 15
Swelling (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	25 / 97 (25.77%) 25	17 / 73 (23.29%) 17	32 / 144 (22.22%) 32
Swelling (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	20 / 94 (21.28%) 20	16 / 72 (22.22%) 16	29 / 143 (20.28%) 29
Swelling (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	9 / 94 (9.57%) 9	2 / 69 (2.90%) 2	8 / 141 (5.67%) 8
Swelling (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[14]	0 / 90 (0.00%)	0 / 68 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Redness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	41 / 103 (39.81%)	27 / 76 (35.53%)	52 / 149 (34.90%)
occurrences (all)	41	27	52
Redness (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	31 / 99 (31.31%)	25 / 74 (33.78%)	46 / 146 (31.51%)
occurrences (all)	31	25	46
Redness (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	12 / 94 (12.77%)	5 / 70 (7.14%)	14 / 142 (9.86%)
occurrences (all)	12	5	14
Redness (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 90 (0.00%)	0 / 68 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Pain in extremity			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	15 / 124 (12.10%)	5 / 112 (4.46%)	12 / 179 (6.70%)
occurrences (all)	17	5	12
Upper respiratory tract infection			
subjects affected / exposed	9 / 124 (7.26%)	9 / 112 (8.04%)	3 / 179 (1.68%)
occurrences (all)	9	9	3
Nasopharyngitis			
subjects affected / exposed	4 / 124 (3.23%)	1 / 112 (0.89%)	1 / 179 (0.56%)
occurrences (all)	4	1	1
Sinusitis			
subjects affected / exposed	3 / 124 (2.42%)	3 / 112 (2.68%)	4 / 179 (2.23%)
occurrences (all)	3	3	4
Rhinitis			
subjects affected / exposed	3 / 124 (2.42%)	0 / 112 (0.00%)	2 / 179 (1.12%)
occurrences (all)	3	0	2
Otitis media acute			
subjects affected / exposed	3 / 124 (2.42%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	3	1	0
Viral infection			

subjects affected / exposed	2 / 124 (1.61%)	1 / 112 (0.89%)	5 / 179 (2.79%)
occurrences (all)	2	1	5
Croup infectious			
subjects affected / exposed	2 / 124 (1.61%)	1 / 112 (0.89%)	2 / 179 (1.12%)
occurrences (all)	2	1	2
Gastroenteritis			
subjects affected / exposed	2 / 124 (1.61%)	0 / 112 (0.00%)	2 / 179 (1.12%)
occurrences (all)	2	0	2
Pharyngitis			
subjects affected / exposed	2 / 124 (1.61%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	2	0	1
Ear infection			
subjects affected / exposed	2 / 124 (1.61%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis viral			
subjects affected / exposed	2 / 124 (1.61%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	2	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 124 (0.81%)	1 / 112 (0.89%)	3 / 179 (1.68%)
occurrences (all)	1	1	3
Bronchitis			
subjects affected / exposed	1 / 124 (0.81%)	1 / 112 (0.89%)	1 / 179 (0.56%)
occurrences (all)	1	1	1
Bronchiolitis			
subjects affected / exposed	1 / 124 (0.81%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	1	1	0
Eye infection			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Lice infestation			

subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Otitis media chronic			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	2	0	0
Paronychia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Pneumonia viral			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Subcutaneous abscess			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	1 / 179 (0.56%)
occurrences (all)	0	0	1
Cellulitis streptococcal			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	0	1	0
Coxsackie viral infection			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	0	1	0
Dermatitis infected			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	0	1	0
Viral rash			

subjects affected / exposed	0 / 124 (0.00%)	1 / 112 (0.89%)	0 / 179 (0.00%)
occurrences (all)	0	1	0
Intertrigo candida			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Urethritis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			

subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 124 (0.00%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0
Lactose intolerance			
subjects affected / exposed	1 / 124 (0.81%)	0 / 112 (0.00%)	0 / 179 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	13vPnC Group 1 (Cohort 2) Dose 1	13vPnC Group 1 (Cohort 2) Dose 2	13vPnC Group 2 (Cohort 2) Dose 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	134 / 175 (76.57%)	99 / 165 (60.00%)	74 / 118 (62.71%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 175 (4.00%)	5 / 165 (3.03%)	4 / 118 (3.39%)
occurrences (all)	7	5	5
Injection site pruritus			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Fever >=38 degrees C but <=39 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	24 / 137 (17.52%)	12 / 101 (11.88%)	13 / 90 (14.44%)
occurrences (all)	24	12	13
Fever >39 degrees C but <=40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e-diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	6 / 130 (4.62%)	2 / 100 (2.00%)	3 / 89 (3.37%)
occurrences (all)	6	2	3
Fever >40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 130 (0.00%)	1 / 98 (1.02%)	1 / 88 (1.14%)
occurrences (all)	0	1	1
Decreased appetite	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	58 / 146 (39.73%)	39 / 113 (34.51%)	32 / 94 (34.04%)
occurrences (all)	58	39	32
Irritability	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	113 / 156 (72.44%)	77 / 126 (61.11%)	53 / 102 (51.96%)
occurrences (all)	113	77	53

Increased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	54 / 146 (36.99%)	26 / 109 (23.85%)	23 / 97 (23.71%)
occurrences (all)	54	26	23
Decreased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	45 / 140 (32.14%)	30 / 112 (26.79%)	17 / 91 (18.68%)
occurrences (all)	45	30	17
Hives (urticaria)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	2 / 131 (1.53%)	0 / 98 (0.00%)	4 / 88 (4.55%)
occurrences (all)	2	0	4
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	2	0	0
Seasonal allergy			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal discomfort			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Penile adhesion			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	6 / 175 (3.43%)	7 / 165 (4.24%)	3 / 118 (2.54%)
occurrences (all)	6	7	4
Rhinorrhoea			
subjects affected / exposed	5 / 175 (2.86%)	4 / 165 (2.42%)	3 / 118 (2.54%)
occurrences (all)	5	4	4
Epistaxis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	2 / 175 (1.14%)	2 / 165 (1.21%)	1 / 118 (0.85%)
occurrences (all)	2	2	1
Pneumonitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	3 / 118 (2.54%)
occurrences (all)	0	1	3
Oropharyngeal pain			
subjects affected / exposed	1 / 175 (0.57%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	1	1	0
Rhinitis allergic			
subjects affected / exposed	2 / 175 (1.14%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	2	1	0
Bronchospasm			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Interstitial lung disease			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0

Bronchial hyperreactivity			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	1 / 118 (0.85%)
occurrences (all)	0	1	1
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Sneezing			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Asperger's disorder			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Heart rate decreased			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Skin laceration			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Excoriation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Lower limb fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Laceration			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Mouth injury			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Burns second degree			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Traumatic brain injury			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Ulna fracture			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0

Periorbital haematoma			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	2 / 118 (1.69%)
occurrences (all)	0	0	2
Speech disorder developmental			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 175 (0.57%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	1	1	0
Leukocytosis			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	3 / 175 (1.71%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	3	1	0
Eustachian tube dysfunction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	2 / 175 (1.14%)	3 / 165 (1.82%)	0 / 118 (0.00%)
occurrences (all)	2	3	0
Hypermetropia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Eye swelling			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Myopia			

subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 175 (1.14%)	3 / 165 (1.82%)	3 / 118 (2.54%)
occurrences (all)	2	3	3
Diarrhoea			
subjects affected / exposed	6 / 175 (3.43%)	3 / 165 (1.82%)	2 / 118 (1.69%)
occurrences (all)	6	3	2
Constipation			
subjects affected / exposed	2 / 175 (1.14%)	1 / 165 (0.61%)	1 / 118 (0.85%)
occurrences (all)	2	1	1
Tongue coated			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Duodenogastric reflux			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 175 (0.00%)	2 / 165 (1.21%)	0 / 118 (0.00%)
occurrences (all)	0	2	0
Lip dry			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Teething			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0

Toothache			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Uvulitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	5 / 175 (2.86%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	5	0	1
Dermatitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	6 / 175 (3.43%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	6	1	0
Eczema			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	1 / 118 (0.85%)
occurrences (all)	0	1	1
Skin disorder			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	1 / 175 (0.57%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Acne			

subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Acanthosis nigricans			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Tenderness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	67 / 148 (45.27%)	69 / 125 (55.20%)	64 / 102 (62.75%)
occurrences (all)	67	69	64
Tenderness (significant)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	7 / 133 (5.26%)	10 / 101 (9.90%)	12 / 92 (13.04%)
occurrences (all)	7	10	12
Swelling (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	25 / 142 (17.61%)	18 / 105 (17.14%)	18 / 90 (20.00%)
occurrences (all)	25	18	18
Swelling (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	20 / 141 (14.18%)	16 / 104 (15.38%)	12 / 89 (13.48%)
occurrences (all)	20	16	12
Swelling (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[13]	10 / 135 (7.41%)	8 / 102 (7.84%)	10 / 89 (11.24%)
occurrences (all)	10	8	10
Swelling (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 131 (0.00%)	0 / 98 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Redness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	27 / 143 (18.88%)	26 / 110 (23.64%)	33 / 91 (36.26%)
occurrences (all)	27	26	33
Redness (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	24 / 143 (16.78%)	20 / 108 (18.52%)	28 / 90 (31.11%)
occurrences (all)	24	20	28
Redness (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	8 / 135 (5.93%)	6 / 100 (6.00%)	13 / 89 (14.61%)
occurrences (all)	8	6	13
Redness (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	1 / 131 (0.76%)	0 / 98 (0.00%)	1 / 88 (1.14%)
occurrences (all)	1	0	1
Renal and urinary disorders			

Dysuria			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	12 / 175 (6.86%)	11 / 165 (6.67%)	1 / 118 (0.85%)
occurrences (all)	12	11	1
Upper respiratory tract infection			
subjects affected / exposed	15 / 175 (8.57%)	14 / 165 (8.48%)	1 / 118 (0.85%)
occurrences (all)	16	14	1
Nasopharyngitis			
subjects affected / exposed	7 / 175 (4.00%)	2 / 165 (1.21%)	3 / 118 (2.54%)
occurrences (all)	7	2	3
Sinusitis			
subjects affected / exposed	4 / 175 (2.29%)	1 / 165 (0.61%)	2 / 118 (1.69%)
occurrences (all)	5	1	2
Rhinitis			

subjects affected / exposed	8 / 175 (4.57%)	3 / 165 (1.82%)	0 / 118 (0.00%)
occurrences (all)	10	3	0
Otitis media acute			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	2	0	0
Viral infection			
subjects affected / exposed	4 / 175 (2.29%)	3 / 165 (1.82%)	3 / 118 (2.54%)
occurrences (all)	4	3	3
Croup infectious			
subjects affected / exposed	7 / 175 (4.00%)	1 / 165 (0.61%)	1 / 118 (0.85%)
occurrences (all)	7	1	1
Gastroenteritis			
subjects affected / exposed	2 / 175 (1.14%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	2	1	0
Pharyngitis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	3 / 118 (2.54%)
occurrences (all)	0	1	3
Ear infection			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 175 (1.14%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	3 / 175 (1.71%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	5	0	0
Bronchiolitis			
subjects affected / exposed	2 / 175 (1.14%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	2	1	0
Eye infection			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Impetigo			

subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	2 / 175 (1.14%)	0 / 165 (0.00%)	2 / 118 (1.69%)
occurrences (all)	2	0	2
Lice infestation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Pneumonia viral			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Cellulitis streptococcal			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			

subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	2 / 175 (1.14%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	2	1	0
Viral rash			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Intertrigo candida			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Urethritis			
subjects affected / exposed	1 / 175 (0.57%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Erythema infectiosum			
subjects affected / exposed	0 / 175 (0.00%)	2 / 165 (1.21%)	0 / 118 (0.00%)
occurrences (all)	0	3	0
Folliculitis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 175 (0.00%)	1 / 165 (0.61%)	0 / 118 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			

subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 175 (0.00%)	0 / 165 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	6-Month Follow-up 13vPnC Group 1 (Cohort 1 and 2)	6-Month Follow-up 13vPnC Group 2 (Cohort 1 and 2)	13vPnC Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 299 (0.67%)	2 / 297 (0.67%)	242 / 294 (82.31%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	7 / 294 (2.38%)
occurrences (all)	0	0	7
Injection site pruritus			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Fever >=38 degrees C but <=39 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 299 (0.00%)	0 / 297 (0.00%)	9 / 212 (4.25%)
occurrences (all)	0	0	9
Fever >39 degrees C but <=40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e-diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 299 (0.00%)	0 / 297 (0.00%)	5 / 212 (2.36%)
occurrences (all)	0	0	5
Fever >40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 210 (0.48%)
occurrences (all)	0	0	1
Decreased appetite	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 299 (0.00%)	0 / 297 (0.00%)	52 / 227 (22.91%)
occurrences (all)	0	0	52

Irritability	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 299 (0.00%)	0 / 297 (0.00%)	73 / 234 (31.20%)
occurrences (all)	0	0	73
Increased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 299 (0.00%)	0 / 297 (0.00%)	48 / 226 (21.24%)
occurrences (all)	0	0	48
Decreased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 299 (0.00%)	0 / 297 (0.00%)	12 / 212 (5.66%)
occurrences (all)	0	0	12
Hives (urticaria)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 299 (0.00%)	0 / 297 (0.00%)	4 / 213 (1.88%)
occurrences (all)	0	0	4
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Vulvovaginal discomfort			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Penile adhesion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	10 / 294 (3.40%)
occurrences (all)	0	0	10
Rhinorrhoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Pneumonitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	2
Oropharyngeal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	1 / 299 (0.33%)	1 / 297 (0.34%)	0 / 294 (0.00%)
occurrences (all)	1	1	0
Bronchospasm			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 299 (0.00%)	1 / 297 (0.34%)	0 / 294 (0.00%)
occurrences (all)	0	1	0
Asperger's disorder			
subjects affected / exposed	0 / 299 (0.00%)	1 / 297 (0.34%)	0 / 294 (0.00%)
occurrences (all)	0	1	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 299 (0.00%)	1 / 297 (0.34%)	0 / 294 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Lower limb fracture			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Traumatic brain injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Ulna fracture			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Eye injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Periorbital haematoma			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3

Speech disorder developmental			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Eustachian tube dysfunction			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	2 / 294 (0.68%)
occurrences (all)	0	0	2
Hypermetropia			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	8 / 294 (2.72%)
occurrences (all)	0	0	9
Diarrhoea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Constipation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Duodenogastric reflux			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Lip dry			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0

Abdominal pain upper			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Uvulitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 299 (0.33%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	1	0	1
Skin disorder			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Acanthosis nigricans			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Tenderness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 299 (0.00%)	0 / 297 (0.00%)	230 / 265 (86.79%)
occurrences (all)	0	0	230
Tenderness (significant)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 299 (0.00%)	0 / 297 (0.00%)	43 / 221 (19.46%)
occurrences (all)	0	0	43
Swelling (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 299 (0.00%)	0 / 297 (0.00%)	85 / 226 (37.61%)
occurrences (all)	0	0	85
Swelling (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local			

Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 299 (0.00%)	0 / 297 (0.00%)	48 / 220 (21.82%)
occurrences (all)	0	0	48
Swelling (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 299 (0.00%)	0 / 297 (0.00%)	48 / 219 (21.92%)
occurrences (all)	0	0	48
Swelling (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 299 (0.00%)	0 / 297 (0.00%)	7 / 211 (3.32%)
occurrences (all)	0	0	7
Redness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 299 (0.00%)	0 / 297 (0.00%)	100 / 233 (42.92%)
occurrences (all)	0	0	100
Redness (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 299 (0.00%)	0 / 297 (0.00%)	63 / 226 (27.88%)
occurrences (all)	0	0	63
Redness (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[17]	0 / 299 (0.00%)	0 / 297 (0.00%)	48 / 218 (22.02%)
occurrences (all)	0	0	48
Redness (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 299 (0.00%)	0 / 297 (0.00%)	7 / 212 (3.30%)
occurrences (all)	0	0	7
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Torticollis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Upper respiratory tract infection			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	2 / 294 (0.68%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Sinusitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Rhinitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Croup infectious			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	2 / 294 (0.68%)
occurrences (all)	0	0	2
Ear infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	2 / 294 (0.68%)
occurrences (all)	0	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Bronchitis			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	3 / 294 (1.02%)
occurrences (all)	0	0	3
Lice infestation			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Cellulitis streptococcal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	6 / 294 (2.04%)
occurrences (all)	0	0	6
Viral rash			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Intertrigo candida			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Urethritis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			

subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Dermatophytosis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Viral pharyngitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	1 / 294 (0.34%)
occurrences (all)	0	0	1
Acute sinusitis			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 299 (0.00%)	0 / 297 (0.00%)	0 / 294 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	6-Month Follow-up 13vPnC Group 3	13vPnC Group 4	6-Month Follow-up 13vPnC Group 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 294 (2.38%)	258 / 298 (86.58%)	4 / 298 (1.34%)
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	0 / 294 (0.00%)	3 / 298 (1.01%)	0 / 298 (0.00%)
occurrences (all)	0	3	0
Injection site pruritus			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Injection site pain			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Fever >=38 degrees C but <=39 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 294 (0.00%)	11 / 214 (5.14%)	0 / 298 (0.00%)
occurrences (all)	0	11	0
Fever >39 degrees C but <=40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e-diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 294 (0.00%)	1 / 212 (0.47%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Fever >40 degrees C	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			

alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 294 (0.00%)	1 / 212 (0.47%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Decreased appetite	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 294 (0.00%)	51 / 223 (22.87%)	0 / 298 (0.00%)
occurrences (all)	0	51	0
Irritability	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 294 (0.00%)	59 / 234 (25.21%)	0 / 298 (0.00%)
occurrences (all)	0	59	0
Increased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 294 (0.00%)	61 / 229 (26.64%)	0 / 298 (0.00%)
occurrences (all)	0	61	0
Decreased sleep	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 294 (0.00%)	42 / 224 (18.75%)	0 / 298 (0.00%)
occurrences (all)	0	42	0
Hives (urticaria)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 294 (0.00%)	3 / 214 (1.40%)	0 / 298 (0.00%)
occurrences (all)	0	3	0
Immune system disorders			

Drug hypersensitivity			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal discomfort			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Penile adhesion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 294 (0.00%)	5 / 298 (1.68%)	0 / 298 (0.00%)
occurrences (all)	0	5	0
Rhinorrhoea			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Asthma			

subjects affected / exposed	2 / 294 (0.68%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	2	2	0
Oropharyngeal pain			
subjects affected / exposed	0 / 294 (0.00%)	5 / 298 (1.68%)	0 / 298 (0.00%)
occurrences (all)	0	5	0
Rhinitis allergic			
subjects affected / exposed	1 / 294 (0.34%)	0 / 298 (0.00%)	1 / 298 (0.34%)
occurrences (all)	1	0	1
Bronchospasm			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Interstitial lung disease			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	2 / 294 (0.68%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	2	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Asperger's disorder			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Attention deficit/hyperactivity disorder			

subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	1 / 298 (0.34%)
occurrences (all)	0	1	1
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Heart rate decreased			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Lower limb fracture			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Laceration			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Burns second degree			

subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Traumatic brain injury			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Ulna fracture			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Periorbital haematoma			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Foot fracture			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Wrist fracture			

subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 294 (0.00%)	10 / 298 (3.36%)	0 / 298 (0.00%)
occurrences (all)	0	11	0
Speech disorder developmental			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Migraine			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	1 / 298 (0.34%)
occurrences (all)	0	1	1
Somnolence			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Eustachian tube dysfunction			

subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Hypermetropia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	1 / 294 (0.34%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 294 (0.00%)	4 / 298 (1.34%)	0 / 298 (0.00%)
occurrences (all)	0	4	0
Diarrhoea			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	1 / 298 (0.34%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Tongue coated			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Duodenogastric reflux			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Lip dry			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 294 (0.00%)	3 / 298 (1.01%)	0 / 298 (0.00%)
occurrences (all)	0	3	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 294 (0.34%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Uvulitis			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0

Eczema			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Acanthosis nigricans			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Tenderness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 294 (0.00%)	252 / 283 (89.05%)	0 / 298 (0.00%)
occurrences (all)	0	252	0
Tenderness (significant)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 294 (0.00%)	106 / 242 (43.80%)	0 / 298 (0.00%)
occurrences (all)	0	106	0
Swelling (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		

alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	0 / 294 (0.00%) 0	86 / 233 (36.91%) 86	0 / 298 (0.00%) 0
Swelling (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	0 / 294 (0.00%) 0	50 / 221 (22.62%) 50	0 / 298 (0.00%) 0
Swelling (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	0 / 294 (0.00%) 0	48 / 226 (21.24%) 48	0 / 298 (0.00%) 0
Swelling (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	0 / 294 (0.00%) 0	4 / 214 (1.87%) 4	0 / 298 (0.00%) 0
Redness (any)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[15] occurrences (all)	0 / 294 (0.00%) 0	70 / 232 (30.17%) 70	0 / 298 (0.00%) 0
Redness (mild)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic			

subjects affected / exposed[16]	0 / 294 (0.00%)	48 / 226 (21.24%)	0 / 298 (0.00%)
occurrences (all)	0	48	0
Redness (moderate)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 294 (0.00%)	31 / 221 (14.03%)	0 / 298 (0.00%)
occurrences (all)	0	31	0
Redness (severe)	Additional description: Subjects affected and occurrences for LR and SE is same as e--diaries could not distinguish 1 occurrence from other within a subject/vaccination. Dictionary version not captured, hence 0.0 is mentioned.LR and SE not assessed during 6-month follow-up.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 294 (0.00%)	4 / 213 (1.88%)	0 / 298 (0.00%)
occurrences (all)	0	4	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 294 (0.00%)	3 / 298 (1.01%)	0 / 298 (0.00%)
occurrences (all)	0	3	0
Nasopharyngitis			
subjects affected / exposed	0 / 294 (0.00%)	3 / 298 (1.01%)	0 / 298 (0.00%)
occurrences (all)	0	3	0
Sinusitis			
subjects affected / exposed	0 / 294 (0.00%)	5 / 298 (1.68%)	0 / 298 (0.00%)
occurrences (all)	0	5	0
Rhinitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 294 (0.00%)	4 / 298 (1.34%)	0 / 298 (0.00%)
occurrences (all)	0	4	0
Croup infectious			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 294 (0.00%)	5 / 298 (1.68%)	0 / 298 (0.00%)
occurrences (all)	0	5	0
Ear infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis viral			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Bronchiolitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 294 (0.00%)	5 / 298 (1.68%)	0 / 298 (0.00%)
occurrences (all)	0	5	0
Lice infestation			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0

Skin infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Cellulitis streptococcal			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Intertrigo candida			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Urethritis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 294 (0.00%)	2 / 298 (0.67%)	0 / 298 (0.00%)
occurrences (all)	0	2	0

Erythema infectiosum			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Furuncle			
subjects affected / exposed	0 / 294 (0.00%)	1 / 298 (0.34%)	0 / 298 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	0 / 294 (0.00%)	0 / 298 (0.00%)	0 / 298 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			

subjects affected / exposed occurrences (all)	0 / 294 (0.00%) 0	0 / 298 (0.00%) 0	0 / 298 (0.00%) 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.

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

for all days.

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

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

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

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

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 June 2009	1- The sample size was increased to 300 subjects in each group to enhance the immunogenicity and safety assessments. 2- An OPA analysis on a subset of subjects in groups 3 and 4 was added. 3- The total volume of blood collected was increased to 10 mL.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported