Clinical trial results:
A Phase 3, Open-label, Single-Arm Trial to Evaluate the Safety, Tolerability, and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine in Children With Sickle Cell Disease Previously Immunized With 23-valent Pneumococcal Polysaccharide Vaccine

Summary

EudraCT number	2009-011396-77
Trial protocol	FR GB IT Outside EU/EEA
Global end of trial date	28 March 2013

Results information

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

Trial information

Trial identification

Sponsor protocol code	B1851013 (6096A1-3014)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00918580
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 June 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 March 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immune response 1 month after 2 doses of 13-valent pneumococcal conjugate vaccine (13vPnC) given 6 months apart compared to 1 month after 1 dose of 13vPnC as measured by fold rise in serotype specific immunoglobulin G (IgG) geometric mean concentrations (GMCs) in children with sickle cell disease (SCD) who had been previously vaccinated with at least 1 dose of 23-valent pneumococcal polysaccharide vaccine (23vPS).

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	03 November 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 27
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Italy: 11
Country: Number of subjects enrolled	Saudi Arabia: 3
Country: Number of subjects enrolled	Lebanon: 56
Country: Number of subjects enrolled	Egypt: 23
Country: Number of subjects enrolled	United States: 29
Worldwide total number of subjects	158
EEA total number of subjects	47

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	53
Adolescents (12-17 years)	105
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:

This study was conducted in the United States of America (USA), United Kingdom, Italy, Lebanon, Egypt, France, and Saudi Arabia. Children with sickle cell disease, of 6 years to less than 18 years of age, previously immunized with 23vPS at least 6 months ago, were enrolled in this study.

Period 1

Period 1 title	Up to 6-month Follow-up (FU)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	13vPnC

Arm description:

Subjects previously immunized with 23vPS received 2 single 0.5 milliliter (mL) doses of 13vPnC intramuscular injection, 6 months apart.

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

Dosage and administration details:

Subjects received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart.

Number of subjects in period 1	13vPnC
Started	158
Vaccinated Dose 1	158
Vaccinated Dose 2	146 [1]
Completed	147
Not completed	11
Consent withdrawn by subject	2
'Parent/Legal Guardian Request '	2
Adverse event, non-fatal	1
'Failed to Return '	1
Lost to follow-up	5

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: This milestone included 1 subject who withdrew before Dose 2 (protocol violation) but completed 6-month follow-up period.

Period 2	
Period 2 title	After 6-month FU to 1-year FU
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Arm title	13vPnC

Arm description:

Subjects previously immunized with 23vPS received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart in Period 1.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	13vPnC
Started	147
Continued After 6-Month FU	89
Completed	87
Not completed	60
'Did Not Continue After 6-Month FU '	58
'Failed to Return '	2

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC
Reporting group description:	
Subjects previously immunized with 23vPS received 2 single 0.5 milliliter (mL) doses of 13vPnC intramuscular injection, 6 months apart.	

Reporting group values	13vPnC	Total	
Number of subjects	158	158	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	13.3		
standard deviation	± 3.08	-	
Gender categorical			
Units: Subjects			
Female	76	76	
Male	82	82	

End points

End points reporting groups

Reporting group title	13vPnC
Reporting group description:	
Subjects previously immunized with 23vPS received 2 single 0.5 milliliter (mL) doses of 13vPnC intramuscular injection, 6 months apart.	

Reporting group title	13vPnC
Reporting group description:	
Subjects previously immunized with 23vPS received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart in Period 1.	

Primary: Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 1 Month After 13vPnC Dose 1 to 1 Month After 13vPnC Dose 2

End point title	Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 1 Month After 13vPnC Dose 1 to 1 Month After 13vPnC Dose 2[1]
End point description:	
GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 1 to 1 month after 13vPnC Dose 2 were computed using logarithmically transformed assay results. Confidence interval (CI) for GMFR were back transformations of a CI based on Student t distribution for mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 1 and after 13vPnC Dose 2 blood draws. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. Here "N" signifies subjects with determinate IgG antibody concentration for the given serotype at both the time points 1 Month After 13vPnC Dose 1 and 1 Month After 13vPnC Dose 2 blood draws. Subjects may be represented in more than 1 category.	
End point type	Primary
End point timeframe:	
1 Month After 13vPnC Dose 1, 1 Month After 13vPnC Dose 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.

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	138[2]			
Units: fold rise				
geometric mean (confidence interval 95%)				
Serotype 4 (N = 137)	0.75 (0.66 to 0.84)			
Serotype 6B (N = 136)	0.89 (0.78 to 1.02)			
Serotype 9V (N = 136)	0.82 (0.75 to 0.91)			
Serotype 14 (N = 137)	0.75 (0.67 to 0.85)			
Serotype 18C (N = 137)	0.7 (0.62 to 0.8)			
Serotype 19F (N = 136)	1.05 (0.91 to 1.2)			

Serotype 23F (N = 135)	0.91 (0.77 to 1.08)			
Serotype 1 (N = 137)	0.88 (0.77 to 0.99)			
Serotype 3 (N = 134)	0.82 (0.75 to 0.9)			
Serotype 5 (N = 136)	0.9 (0.82 to 0.98)			
Serotype 6A (N = 136)	0.95 (0.82 to 1.1)			
Serotype 7F (N = 137)	0.75 (0.67 to 0.85)			
Serotype 19A (N = 137)	0.83 (0.74 to 0.93)			

Notes:

[2] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1

End point title	Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC Dose 1 to 1 month after 13vPnC Dose 1 were computed using logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on Student t distribution for mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from before 13vPnC Dose 1 and 1 month after 13vPnC Dose 1 blood draws. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subjects with a determinate IgG antibody concentration for given serotype from before 13vPnC Dose 1 and 1 month after 13vPnC Dose 1 blood draws. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	138[3]			
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 4 (N = 136)	6.91 (5.27 to 9.06)			
Serotype 6B (N = 137)	4.72 (3.8 to 5.85)			
Serotype 9V (N = 138)	3.1 (2.6 to 3.7)			
Serotype 14 (N = 138)	5.5 (4.05 to 7.46)			

Serotype 18C (N = 137)	5.58 (4.47 to 6.97)			
Serotype 19F (N = 134)	4.76 (3.77 to 6.03)			
Serotype 23F (N = 137)	6.58 (5.12 to 8.46)			
Serotype 1 (N = 129)	3.6 (2.9 to 4.46)			
Serotype 3 (N = 133)	2.03 (1.78 to 2.31)			
Serotype 5 (N = 138)	1.74 (1.56 to 1.94)			
Serotype 6A (N = 132)	4.1 (3.32 to 5.05)			
Serotype 7F (N = 137)	4.38 (3.62 to 5.3)			
Serotype 19A (N = 138)	3.28 (2.73 to 3.96)			

Notes:

[3] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 2 to 1 Month After 13vPnC Dose 2

End point title	Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 2 to 1 Month After 13vPnC Dose 2

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC Dose 2 to 1 month after 13vPnC Dose 2 were computed using logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on Student t distribution for mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from before 13vPnC Dose 2 and 1 month after 13vPnC Dose 2 blood draws. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with a determinate IgG antibody concentration for given serotype from before 13vPnC Dose 2 and 1 month after 13vPnC Dose 2 blood draws. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	138[4]			
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 4 (N = 137)	1.86 (1.69 to 2.04)			

Serotype 6B (N = 137)	1.8 (1.69 to 2.03)			
Serotype 9V (N = 136)	1.48 (1.37 to 1.59)			
Serotype 14 (N = 137)	1.24 (1.15 to 1.35)			
Serotype 18C (N = 137)	1.47 (1.34 to 1.62)			
Serotype 19F (N = 135)	2.08 (1.85 to 2.34)			
Serotype 23F (N = 135)	2.04 (1.75 to 2.37)			
Serotype 1 (N = 136)	1.73 (1.57 to 1.92)			
Serotype 3 (N = 133)	1.36 (1.25 to 1.47)			
Serotype 5 (N = 135)	1.3 (1.22 to 1.39)			
Serotype 6A (N = 133)	1.8 (1.6 to 2.02)			
Serotype 7F (N = 137)	1.75 (1.61 to 1.9)			
Serotype 19A (N = 137)	1.48 (1.36 to 1.61)			

Notes:

[4] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 13vPnC Dose 1 to 13vPnC Dose 2

End point title	Ratio of Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 13vPnC Dose 1 to 13vPnC Dose 2

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were computed using the logarithmically transformed assay results for Dose 1 (after Dose 1/before Dose 1) and for Dose 2 (after Dose 2/before Dose 2). CI for the ratio of GMFR (Dose 2/Dose 1) were back transformations of a CI based on the Student t distribution for the mean logarithm of the measures (Dose 2 – Dose 1). Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with a determinate IgG antibody concentration for given serotype at before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2 and 1 month after 13vPnC Dose 2 blood draws. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	138[5]			
Units: Ratio of GMFR				
geometric mean (confidence interval 95%)				
Serotype 4 (N = 135)	0.26 (0.2 to 0.35)			
Serotype 6B (N = 136)	0.38 (0.29 to 0.49)			
Serotype 9V (N = 136)	0.49 (0.41 to 0.59)			
Serotype 14 (N = 137)	0.22 (0.16 to 0.31)			
Serotype 18C (N = 136)	0.26 (0.21 to 0.34)			
Serotype 19F (N = 132)	0.44 (0.34 to 0.57)			
Serotype 23F (N = 135)	0.32 (0.24 to 0.43)			
Serotype 1 (N = 127)	0.47 (0.37 to 0.59)			
Serotype 3 (N = 130)	0.66 (0.58 to 0.75)			
Serotype 5 (N = 135)	0.75 (0.66 to 0.85)			
Serotype 6A (N = 127)	0.45 (0.35 to 0.58)			
Serotype 7F (N = 136)	0.39 (0.32 to 0.49)			
Serotype 19A (N = 137)	0.45 (0.36 to 0.55)			

Notes:

[5] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody

End point title	Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) CIs were evaluated. Geometric means were calculated using all subjects with available data for the specified blood draw. CI for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with determinate IgG antibody concentration for the given serotype at specified time point. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	138[6]			
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				
Before 13vPnC Dose 1: Serotype 4 (N = 136)	1.01 (0.8 to 1.27)			
Before 13vPnC Dose 1: Serotype 6B (N = 138)	5.79 (4.89 to 6.87)			
Before 13vPnC Dose 1: Serotype 9V (N = 138)	3.01 (2.56 to 3.53)			
Before 13vPnC Dose 1: Serotype 14 (N = 138)	6.3 (4.78 to 8.3)			
Before 13vPnC Dose 1: Serotype 18C (N = 137)	1.4 (1.14 to 1.73)			
Before 13vPnC Dose 1: Serotype 19F (N = 134)	4.46 (3.6 to 5.53)			
Before 13vPnC Dose 1: Serotype 23F (N = 138)	2.8 (2.38 to 3.3)			
Before 13vPnC Dose 1: Serotype 1 (N = 129)	1.57 (1.26 to 1.95)			
Before 13vPnC Dose 1: Serotype 3 (N = 133)	1.02 (0.83 to 1.25)			
Before 13vPnC Dose 1: Serotype 5 (N = 138)	4.14 (3.58 to 4.78)			
Before 13vPnC Dose 1: Serotype 6A (N = 132)	4.62 (3.91 to 5.46)			
Before 13vPnC Dose 1: Serotype 7F (N = 137)	2.16 (1.8 to 2.59)			
Before 13vPnC Dose 1: Serotype 19A (N = 138)	8.16 (7.03 to 9.48)			
1 Month After 13vPnC Dose 1: Serotype 4 (N = 138)	6.85 (5.55 to 8.44)			
1 Month After 13vPnC Dose 1: Serotype 6B (N= 137)	27.25 (22.09 to 33.61)			
1 Month After 13vPnC Dose 1: Serotype 9V (N= 138)	9.31 (7.83 to 11.07)			
1 Month After 13vPnC Dose 1: Serotype 14 (N = 138)	34.63 (27.77 to 43.18)			
1 Month After 13vPnC Dose 1: Serotype 18C (N= 138)	7.83 (6.42 to 9.54)			
1 Month After 13vPnC Dose 1: Serotype 19F (N= 138)	20.4 (16.03 to 25.95)			
1 Month After 13vPnC Dose 1: Serotype 23F (N= 137)	18.25 (14.52 to 22.95)			
1 Month After 13vPnC Dose 1: Serotype 1 (N = 138)	5.24 (4.3 to 6.39)			
1 Month After 13vPnC Dose 1: Serotype 3 (N = 138)	2.04 (1.76 to 2.38)			
1 Month After 13vPnC Dose 1: Serotype 5 (N = 138)	7.19 (6.19 to 8.35)			
1 Month After 13vPnC Dose 1: Serotype 6A (N = 138)	17.61 (14.16 to 21.91)			
1 Month After 13vPnC Dose 1: Serotype 7F (N = 138)	9.46 (8.17 to 10.94)			

1 Month After 13vPnC Dose 1: Serotype 19A (N= 138)	26.82 (22.16 to 32.46)			
Before 13vPnC Dose 2: Serotype 4 (N = 138)	2.77 (2.29 to 3.35)			
Before 13vPnC Dose 2: Serotype 6B (N = 138)	13.67 (11.23 to 16.63)			
Before 13vPnC Dose 2: Serotype 9V (N = 138)	5.19 (4.41 to 6.09)			
Before 13vPnC Dose 2: Serotype 14 (N = 138)	21.07 (17.29 to 25.67)			
Before 13vPnC Dose 2: Serotype 18C (N = 138)	3.73 (3.1 to 4.49)			
Before 13vPnC Dose 2: Serotype 19F (N = 137)	10.34 (8.32 to 12.85)			
Before 13vPnC Dose 2: Serotype 23F (N = 137)	8.07 (6.63 to 9.83)			
Before 13vPnC Dose 2: Serotype 1 (N = 137)	2.65 (2.21 to 3.19)			
Before 13vPnC Dose 2: Serotype 3 (N = 135)	1.27 (1.06 to 1.52)			
Before 13vPnC Dose 2: Serotype 5 (N = 137)	4.91 (4.26 to 5.66)			
Before 13vPnC Dose 2: Serotype 6A (N = 135)	9.05 (7.48 to 10.95)			
Before 13vPnC Dose 2: Serotype 7F (N = 138)	4.09 (3.52 to 4.74)			
Before 13vPnC Dose 2: Serotype 19A (N = 138)	15.13 (12.73 to 17.98)			
1 Month After 13vPnC Dose 2: Serotype 4 (N = 137)	5.09 (4.28 to 6.04)			
1 Month After 13vPnC Dose 2: Serotype 6B (N= 137)	24.52 (20.48 to 29.35)			
1 Month After 13vPnC Dose 2: Serotype 9V (N= 136)	7.46 (6.46 to 8.61)			
1 Month After 13vPnC Dose 2: Serotype 14 (N = 137)	26.19 (22.11 to 31.03)			
1 Month After 13vPnC Dose 2: Serotype 18C (N= 137)	5.44 (4.64 to 6.38)			
1 Month After 13vPnC Dose 2: Serotype 19F (N= 136)	20.56 (17.15 to 24.63)			
1 Month After 13vPnC Dose 2: Serotype 23F (N= 135)	16.18 (13.27 to 19.73)			
1 Month After 13vPnC Dose 2: Serotype 1 (N = 137)	4.51 (3.82 to 5.32)			
1 Month After 13vPnC Dose 2: Serotype 3 (N = 134)	1.67 (1.42 to 1.97)			
1 Month After 13vPnC Dose 2: Serotype 5 (N = 136)	6.33 (5.58 to 7.17)			
1 Month After 13vPnC Dose 2: Serotype 6A (N = 136)	16.37 (13.65 to 19.64)			
1 Month After 13vPnC Dose 2: Serotype 7F (N = 137)	7.06 (6.2 to 8.04)			
1 Month After 13vPnC Dose 2: Serotype 19A (N= 137)	22.19 (18.94 to 25.99)			

Notes:

[6] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Year After 13vPnC Dose 2

End point title	Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Year After 13vPnC Dose 2

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) are presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) CIs were evaluated. Geometric means were calculated using all subjects with available data for the specified blood draw. CI for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Analysis was done on the evaluable immunogenicity population at 1 year follow up-eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subjects with a determinate IgG antibody concentration for given serotype. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

1 year after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	81[7]			
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 4 (N = 81)	1.94 (1.51 to 2.48)			
Serotype 6B (N = 81)	11.77 (9.43 to 14.71)			
Serotype 9V (N = 81)	4.5 (3.61 to 5.62)			
Serotype 14 (N = 81)	15.89 (12.47 to 20.26)			
Serotype 18C (N = 81)	2.64 (2.03 to 3.42)			
Serotype 19F (N = 81)	9.87 (7.5 to 13)			
Serotype 23F (N = 81)	7.7 (6.15 to 9.63)			
Serotype 1 (N = 79)	2.12 (1.65 to 2.71)			
Serotype 3 (N = 67)	1.01 (0.77 to 1.33)			
Serotype 5 (N = 81)	4.38 (3.58 to 5.37)			
Serotype 6A (N = 81)	7.94 (6.45 to 9.77)			
Serotype 7F (N = 81)	3.47 (2.84 to 4.25)			
Serotype 19A (N = 81)	13.3 (10.62 to 16.65)			

Notes:

[7] - Number of subjects analyzed signifies the evaluable immunogenicity population at 1-year follow-up.

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT)

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT)

End point description:

Antibody GMTs as measured by OPA assay for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). GMT and corresponding 2-sided 95% CIs were evaluated. CIs for the GMTs are back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the titers. GMTs were calculated using all subjects with available data for the specified blood draw. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with determinate OPA antibody titer for the given serotype at specified time point. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	138[8]			
Units: Titer				
geometric mean (confidence interval 95%)				
Before 13vPnC Dose 1: Serotype 4 (N = 105)	215 (129.6 to 357.2)			
Before 13vPnC Dose 1: Serotype 6B (N = 105)	626 (377.5 to 1037.4)			
Before 13vPnC Dose 1: Serotype 9V (N = 109)	234 (137.6 to 398.7)			
Before 13vPnC Dose 1: Serotype 14 (N = 115)	628 (425.8 to 925.7)			
Before 13vPnC Dose 1: Serotype 18C (N = 95)	426 (235.7 to 771.4)			
Before 13vPnC Dose 1: Serotype 19F (N = 96)	94 (55 to 160.7)			
Before 13vPnC Dose 1: Serotype 23F (N = 106)	34 (21.5 to 54.8)			
Before 13vPnC Dose 1: Serotype 1 (N = 131)	7 (5.7 to 8.8)			
Before 13vPnC Dose 1: Serotype 3 (N = 107)	13 (10.1 to 17.5)			
Before 13vPnC Dose 1: Serotype 5 (N = 131)	10 (7.8 to 13.9)			

Before 13vPnC Dose 1: Serotype 6A (N = 116)	246 (149 to 404.8)			
Before 13vPnC Dose 1: Serotype 7F (N = 120)	344 (220.5 to 537.9)			
Before 13vPnC Dose 1: Serotype 19A (N = 127)	137 (100 to 187.4)			
1 Month After 13vPnC Dose 1: Serotype 4 (N = 108)	2670 (2128.1 to 3351.1)			
1 Month After 13vPnC Dose 1: Serotype 6B (N= 116)	7535 (6320.5 to 8983.5)			
1 Month After 13vPnC Dose 1: Serotype 9V (N= 103)	2312 (1684 to 3172.8)			
1 Month After 13vPnC Dose 1: Serotype 14 (N = 117)	2288 (1906.6 to 2745)			
1 Month After 13vPnC Dose 1: Serotype 18C (N= 103)	4326 (3250.3 to 5756.8)			
1 Month After 13vPnC Dose 1: Serotype 19F (N = 89)	1429 (1043.5 to 1957.3)			
1 Month After 13vPnC Dose 1: Serotype 23F (N= 106)	1607 (1227.4 to 2102.7)			
1 Month After 13vPnC Dose 1: Serotype 1 (N = 123)	56 (41 to 77.4)			
1 Month After 13vPnC Dose 1: Serotype 3 (N = 112)	115 (93 to 142.1)			
1 Month After 13vPnC Dose 1: Serotype 5 (N = 121)	277 (198.4 to 385.8)			
1 Month After 13vPnC Dose 1: Serotype 6A (N = 117)	7845 (6581.6 to 9349.9)			
1 Month After 13vPnC Dose 1: Serotype 7F (N = 123)	3348 (2881.9 to 3888.5)			
1 Month After 13vPnC Dose 1: Serotype 19A (N =118)	1449 (1164.2 to 1804.3)			
Before 13vPnC Dose 2: Serotype 4 (N = 104)	1331 (1013.9 to 1748.1)			
Before 13vPnC Dose 2: Serotype 6B (N = 108)	4174 (3513 to 4958.3)			
Before 13vPnC Dose 2: Serotype 9V (N = 99)	1445 (1051.7 to 1985.5)			
Before 13vPnC Dose 2: Serotype 14 (N = 106)	1652 (1347.8 to 2024.1)			
Before 13vPnC Dose 2: Serotype 18C (N = 101)	1928 (1281.1 to 2901)			
Before 13vPnC Dose 2: Serotype 19F (N = 92)	516 (338.8 to 785.5)			
Before 13vPnC Dose 2: Serotype 23F (N = 94)	897 (619 to 1300.4)			
Before 13vPnC Dose 2: Serotype 1 (N = 107)	23 (17.1 to 32.3)			
Before 13vPnC Dose 2: Serotype 3 (N = 120)	56 (45.5 to 69.9)			
Before 13vPnC Dose 2: Serotype 5 (N = 107)	98 (69.2 to 140.2)			
Before 13vPnC Dose 2: Serotype 6A (N = 113)	4005 (3350.6 to 4786.3)			
Before 13vPnC Dose 2: Serotype 7F (N = 112)	1791 (1427 to 2248.6)			
Before 13vPnC Dose 2: Serotype 19A (N = 108)	677 (544.4 to 843.1)			
1 Month After 13vPnC Dose 2: Serotype 4 (N = 105)	3051 (2536.7 to 3670.3)			
1 Month After 13vPnC Dose 2: Serotype 6B (N= 107)	7601 (6392.6 to 9038.6)			

1 Month After 13vPnC Dose 2: Serotype 9V (N = 96)	3467 (2784 to 4317.6)			
1 Month After 13vPnC Dose 2: Serotype 14 (N = 110)	2081 (1770.5 to 2446)			
1 Month After 13vPnC Dose 2: Serotype 18C (N= 103)	5271 (4267.8 to 6510.1)			
1 Month After 13vPnC Dose 2: Serotype 19F (N = 89)	1507 (1139.9 to 1992.2)			
1 Month After 13vPnC Dose 2: Serotype 23F (N= 105)	2330 (1880.4 to 2887)			
1 Month After 13vPnC Dose 2: Serotype 1 (N = 106)	78 (59.5 to 101.2)			
1 Month After 13vPnC Dose 2: Serotype 3 (N = 109)	105 (87.2 to 127.2)			
1 Month After 13vPnC Dose 2: Serotype 5 (N = 118)	273 (213.9 to 349.2)			
1 Month After 13vPnC Dose 2: Serotype 6A (N = 111)	7633 (6439.6 to 9048.6)			
1 Month After 13vPnC Dose 2: Serotype 7F (N = 114)	3723 (3276.2 to 4230.1)			
1 Month After 13vPnC Dose 2: Serotype 19A (N= 115)	1314 (1084.4 to 1592.6)			

Notes:

[8] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Year After 13vPnC Dose 2

End point title	Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Year After 13vPnC Dose 2

End point description:

Antibody GMTs as measured by OPA assay for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). GMT and corresponding 2-sided 95% CIs were evaluated. CIs for the GMTs are back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the titers. GMTs were calculated using all subjects with available data for the specified blood draw. Analysis was done on the evaluable immunogenicity population at 1-year follow up- eligible subjects who received all study vaccinations; had valid and determinate assay result; had blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subjects with determinate OPA antibody titer for the given serotype. Subjects may be represented in more than 1 category.

End point type	Secondary

End point timeframe:

1 year after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	81[9]			
Units: Titer				
geometric mean (confidence interval 95%)				

Serotype 4 (N = 58)	1107 (764.4 to 1602.2)			
Serotype 6B (N = 59)	3412 (2746.4 to 4238.7)			
Serotype 9V (N = 66)	1690 (1157.8 to 2465.5)			
Serotype 14 (N = 64)	1595 (1281.6 to 1984.9)			
Serotype 18C (N = 59)	1604 (1107.2 to 2324.2)			
Serotype 19F (N = 55)	620 (376.6 to 1020.4)			
Serotype 23F (N = 58)	924 (654.2 to 1306.1)			
Serotype 1 (N = 73)	25 (17.5 to 35.4)			
Serotype 3 (N = 72)	31 (22.6 to 42.6)			
Serotype 5 (N = 71)	102 (70.5 to 148)			
Serotype 6A (N = 72)	2485 (1921.2 to 3214.3)			
Serotype 7F (N = 73)	2166 (1861.4 to 2519.3)			
Serotype 19A (N = 73)	589 (449.4 to 771.1)			

Notes:

[9] - Number of subjects analyzed signifies the evaluable immunogenicity population at 1-year follow-up.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 1

End point title	Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 1

End point description:

Specific local reactions were prompted for each day using an electronic diary. Redness and Swelling were scaled as: Any (redness present or swelling present); Mild (less than [<]2.5 centimeters [cm] for subjects aged 6 to <12 years, 2.5 to 5.0 cm for subjects aged greater than or equal to [>=] 12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to <12 years and 5.1 to 10.0 cm for subjects aged >=12 years); Severe (>7 cm for subjects aged 6 to <12 years and >10 cm for subjects aged >=12 years). Pain was scaled as: Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Safety population Dose 1- all subjects who received Dose 1 of study vaccine, had safety dataavailable."N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 7 days after 13vPnC Dose 1

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	158[10]			
Units: Percentage of subjects				
number (not applicable)				
Pain: Any (N = 144)	89.6			
Pain: Mild (N = 132)	81.8			
Pain: Moderate (N = 113)	56.6			
Pain: Severe (N = 90)	11.1			
Redness: Any (N = 93)	23.7			
Redness: Mild (N = 93)	20.4			
Redness: Moderate (N = 90)	8.9			
Redness: Severe (N = 87)	1.1			
Swelling: Any (N = 108)	49.1			
Swelling: Mild (N = 101)	37.6			
Swelling: Moderate (N = 100)	26			
Swelling: Severe (N = 87)	1.1			

Notes:

[10] - Number of subjects analyzed signifies the safety population for Dose 1.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 2

End point title	Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 2

End point description:

Specific local reactions were prompted for each day using an electronic diary. Redness and Swelling were scaled as: Any (redness present or swelling present); Mild (less than <2.5 centimeters [cm] for subjects aged 6 to <12 years, 2.5 to 5.0 cm for subjects aged >= 12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to <12 years and 5.1 to 10.0 cm for subjects aged >=12 years); Severe (>7 cm for subjects aged 6 to <12 years and >10 cm for subjects aged >=12 years). Pain was scaled as: Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Safety population Dose 2- all subjects who received Dose 2 of study vaccine and had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subject may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 7 days after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	140[11]			
Units: Percentage of subjects				
number (not applicable)				
Pain: Any (N = 111)	85.6			
Pain: Mild (N = 103)	77.7			
Pain: Moderate (N = 82)	53.7			

Pain: Severe (N = 69)	15.9			
Redness: Any (N = 67)	26.9			
Redness: Mild (N = 66)	15.2			
Redness: Moderate (N = 64)	14.1			
Redness: Severe (N = 63)	0			
Swelling: Any (N = 84)	53.6			
Swelling: Mild (N = 77)	37.7			
Swelling: Moderate (N = 73)	35.6			
Swelling: Severe (N = 63)	0			

Notes:

[11] - Number of subjects analyzed signifies the safety population for Dose 2.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 1

End point title	Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 1

End point description:

Specific systemic events (fever >=38 degrees Celsius[C], vomiting, diarrhea, headache, fatigue, muscle pain, joint pain, use of antipyretic medications) were reported for each day using an electronic diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours);Moderate(4-5 loose stools 24 hours); Severe(>=6 loose stools in 24 hours). Safety population Dose 1- all subjects who received Dose 1 of study vaccine, had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 7 days after 13vPnC Dose 1

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	158[12]			
Units: Percentage of subjects				
number (not applicable)				
Fever: >=38, =<38.4 degrees C (N = 81)	13.6			
Fever: >38.4, =<38.9 degrees C (N = 82)	7.3			
Fever: >38.9, =<40 degrees C (N = 79)	3.8			
Fever: >40 degrees C (N = 79)	1.3			
Vomiting: Any (N = 91)	15.4			
Vomiting: Mild (N = 89)	11.2			
Vomiting: Moderate (N = 90)	6.7			
Vomiting: Severe (N = 87)	0			
Diarrhea: Any (N = 90)	13.3			
Diarrhea: Mild (N = 87)	6.9			

Diarrhea: Moderate (N = 90)	6.7			
Diarrhea: Severe (N = 87)	2.3			
Headache: Any (N = 110)	53.6			
Headache: Mild (N = 105)	42.9			
Headache: Moderate (N = 101)	34.7			
Headache: Severe (N = 92)	12			
Fatigue: Any (N = 118)	66.1			
Fatigue: Mild (N = 108)	48.1			
Fatigue: Moderate (N = 104)	44.2			
Fatigue: Severe (N = 90)	14.4			
Muscle Pain: Any (N = 127)	74.8			
Muscle Pain: Mild (N = 114)	58.8			
Muscle Pain: Moderate (N = 108)	47.2			
Muscle Pain: Severe (N = 89)	10.1			
Joint Pain: Any (N = 103)	39.8			
Joint Pain: Mild (N = 98)	23.5			
Joint Pain: Moderate (N = 94)	23.4			
Joint Pain: Severe (N = 89)	4.5			
Use of Antipyretic Medications (N = 110)	58.2			

Notes:

[12] - Number of subjects analyzed signifies the safety population for Dose 1.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 2

End point title	Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 2

End point description:

Specific systemic events (fever >=38 degrees Celsius[C], vomiting, diarrhea, headache, fatigue, muscle pain, joint pain, use of antipyretic medications) were reported for each day using an electronic diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours);Moderate(4-5 loose stools 24 hours); Severe(>=6 loose stools in 24 hours). Safety population Dose 2- all subjects who received Dose 2 of study vaccine, had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 7 days after 13vPnC Dose 2

End point values	13vPnC			
Subject group type	Reporting group			
Number of subjects analysed	140[13]			
Units: Percentage of subjects				
number (not applicable)				
Fever: >=38, =<38.4 degrees C (N = 63)	9.5			
Fever: >38.4, =<38.9 degrees C (N = 59)	6.8			
Fever: >38.9, =<40 degrees C (N = 63)	6.3			
Fever: >40 degrees C (N = 60)	1.7			
Vomiting: Any (N = 67)	13.4			
Vomiting: Mild (N = 65)	9.2			
Vomiting: Moderate (N = 64)	4.7			
Vomiting: Severe (N = 64)	1.6			
Diarrhea: Any (N = 68)	25			
Diarrhea: Mild (N = 68)	19.1			
Diarrhea: Moderate (N = 66)	12.1			
Diarrhea: Severe (N = 63)	3.2			
Headache: Any (N = 86)	59.3			
Headache: Mild (N = 74)	41.9			
Headache: Moderate (N = 76)	36.8			
Headache: Severe (N = 66)	10.6			
Fatigue: Any (N = 96)	62.5			
Fatigue: Mild (N = 84)	48.8			
Fatigue: Moderate (N = 83)	41			
Fatigue: Severe (N = 67)	13.4			
Muscle Pain: Any (N = 98)	75.5			
Muscle Pain: Mild (N = 87)	60.9			
Muscle Pain: Moderate (N = 84)	45.2			
Muscle Pain: Severe (N = 67)	16.4			
Joint Pain: Any (N = 78)	44.9			
Joint Pain: Mild (N = 72)	34.7			
Joint Pain: Moderate (N = 70)	21.4			
Joint Pain: Severe (N = 65)	6.2			
Use of Antipyretic Medications (N = 78)	43.6			

Notes:

[13] - Number of subjects analyzed signifies the safety population for Dose 2.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs: Baseline up to 1 year after Dose 2. AEs: 1 month after each 13vPnC dose. Newly diagnosed chronic medical conditions: 6 months after each 13vPnC dose, at 1 year after 13vPnC Dose 2. Local reactions/systemic events: within 7 days after each dose

Adverse event reporting additional description:

Safety population: subjects who received at least 1 dose and had safety data available. AEs included events collected in electronic diary (systematic assessment for local reactions [LR] and systemic events [SE]) and events collected on case report form at each visit (non systematic assessment for SAEs and non-SAEs).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	13vPnC Dose 1

Reporting group description:

Subjects previously immunized with 23vPS who received a single 0.5 mL dose of 13vPnC intramuscular injection on Day 1 (13vPnC Dose 1), assessed between 13vPnC Dose 1 and before 13vPnC Dose2.

Reporting group title	13vPnC Dose 2

Reporting group description:

Subjects previously immunized with 23vPS who received Dose 2 of 0.5 mL 13vPnC intramuscular injection, assessed between 13vPnC Dose 2 and before 13vPnC Dose 2 blood draw.

Reporting group title	6-Month Follow-up

Reporting group description:

Subjects previously immunized with 23vPS who received at least 1 of the 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart, assessed from last 13vPnC Dose (Dose 1 or Dose 2) blood draw to the 6-month follow-up telephone contact.

Reporting group title	1-Year Follow-up

Reporting group description:

Subjects previously immunized with 23vPS who received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart, assessed from the 6-month follow-up telephone contact after 13vPnC Dose 2 to the 1-year follow-up after 13vPnC Dose 2.

Serious adverse events	13vPnC Dose 1	13vPnC Dose 2	6-Month Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	40 / 158 (25.32%)	11 / 140 (7.86%)	28 / 147 (19.05%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Vascular occlusion			
subjects affected / exposed	3 / 158 (1.90%)	2 / 140 (1.43%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal			

conditions			
Pregnancy			
subjects affected / exposed	0 / 158 (0.00%)	2 / 140 (1.43%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 158 (3.16%)	0 / 140 (0.00%)	2 / 147 (1.36%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	0 / 147 (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
Pain			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	2 / 147 (1.36%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Reproductive system and breast disorders			
Priapism			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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			
Acute chest syndrome			

subjects affected / exposed	3 / 158 (1.90%)	0 / 140 (0.00%)	2 / 147 (1.36%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Congenital, familial and genetic disorders			
Sickle cell anaemia with crisis			

subjects affected / exposed	22 / 158 (13.92%)	5 / 140 (3.57%)	17 / 147 (11.56%)
occurrences causally related to treatment / all	0 / 30	0 / 6	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	0 / 147 (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
Cerebral infarction			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unresponsive to stimuli			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Migraine			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Lymphadenopathy			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersplenism			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Visual impairment			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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			
Abdominal pain			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Constipation			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Gastritis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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

Gingivitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Hiatus hernia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Nausea			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Oesophagitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Cholecystitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Hyperbilirubinaemia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal failure			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure chronic			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	1 / 158 (0.63%)	2 / 140 (1.43%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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	1 / 158 (0.63%)	0 / 140 (0.00%)	2 / 147 (1.36%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone abscess			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	0 / 147 (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
Bronchitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Groin abscess			

subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Device related infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Pharyngotonsillitis			

subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Pyelonephritis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (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
Tonsillitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
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	1-Year Follow-up		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 87 (18.39%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Vascular occlusion			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	3 / 87 (3.45%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chest pain				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Priapism				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute chest syndrome				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Lung infiltration			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	11 / 87 (12.64%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 87 (1.15%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			

subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Unresponsive to stimuli				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lethargy				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				

subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersplenism				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Visual impairment				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gingivitis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				

subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis acute				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Haematuria				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure chronic				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysuria				

subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Flank pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in jaw			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			

Pneumonia				
subjects affected / exposed	4 / 87 (4.60%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Bone abscess				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	1 / 87 (1.15%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis A				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				

subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 87 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				

subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	13vPnC Dose 1	13vPnC Dose 2	6-Month Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	133 / 158 (84.18%)	100 / 140 (71.43%)	1 / 147 (0.68%)
Vascular disorders			
Vascular occlusion			
subjects affected / exposed	4 / 158 (2.53%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	5	0	0
Hypertension			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Injection site swelling			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	5 / 158 (3.16%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	5	1	0
Chest pain			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Injection site pain			

subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Asthenia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Injection site movement impairment			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Fever ≥38°C but ≤38.4°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[1]	11 / 81 (13.58%)	6 / 63 (9.52%)	0 / 147 (0.00%)
occurrences (all)	11	6	0
Fever >38.4°C but ≤38.9°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[2]	6 / 82 (7.32%)	4 / 59 (6.78%)	0 / 147 (0.00%)
occurrences (all)	6	4	0
Fever >38.9°C but ≤40.0°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[3]	3 / 79 (3.80%)	4 / 63 (6.35%)	0 / 147 (0.00%)
occurrences (all)	3	4	0
Fever >40.0°C	Additional description: Subjects affected and occurrences for SE is same as data		

	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[4] occurrences (all)	1 / 79 (1.27%) 1	1 / 60 (1.67%) 1	0 / 147 (0.00%) 0
Vomiting (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[5] occurrences (all)	14 / 91 (15.38%) 14	9 / 67 (13.43%) 9	0 / 147 (0.00%) 0
Vomiting (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[6] occurrences (all)	10 / 89 (11.24%) 10	6 / 65 (9.23%) 6	0 / 147 (0.00%) 0
Vomiting (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	6 / 90 (6.67%) 6	3 / 64 (4.69%) 3	0 / 147 (0.00%) 0
Vomiting (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[8] occurrences (all)	0 / 87 (0.00%) 0	1 / 64 (1.56%) 1	0 / 147 (0.00%) 0
Diarrhea (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[9] occurrences (all)	12 / 90 (13.33%) 12	17 / 68 (25.00%) 17	0 / 147 (0.00%) 0
Diarrhea (Mild)	Additional description: Subjects affected and occurrences for SE is same as data		

	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[10] occurrences (all)	6 / 87 (6.90%) 6	13 / 68 (19.12%) 13	0 / 147 (0.00%) 0
Diarrhea (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[11] occurrences (all)	6 / 90 (6.67%) 6	8 / 66 (12.12%) 8	0 / 147 (0.00%) 0
Diarrhea (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[12] occurrences (all)	2 / 87 (2.30%) 2	2 / 63 (3.17%) 2	0 / 147 (0.00%) 0
Headache (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[13] occurrences (all)	59 / 110 (53.64%) 59	51 / 86 (59.30%) 51	0 / 147 (0.00%) 0
Headache (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[14] occurrences (all)	45 / 105 (42.86%) 45	31 / 74 (41.89%) 31	0 / 147 (0.00%) 0
Headache (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[15] occurrences (all)	35 / 101 (34.65%) 35	28 / 76 (36.84%) 28	0 / 147 (0.00%) 0
Headache (Severe)	Additional description: Subjects affected and occurrences for SE is same as data		

	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[16] occurrences (all)	11 / 92 (11.96%) 11	7 / 66 (10.61%) 7	0 / 147 (0.00%) 0
Fatigue (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[17] occurrences (all)	52 / 108 (48.15%) 52	41 / 84 (48.81%) 41	0 / 147 (0.00%) 0
Fatigue (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[18] occurrences (all)	46 / 104 (44.23%) 46	34 / 83 (40.96%) 34	0 / 147 (0.00%) 0
Fatigue (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[19] occurrences (all)	13 / 90 (14.44%) 13	9 / 67 (13.43%) 9	0 / 147 (0.00%) 0
Muscle pain (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[20] occurrences (all)	95 / 127 (74.80%) 95	74 / 98 (75.51%) 74	0 / 147 (0.00%) 0
Muscle pain (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[21] occurrences (all)	67 / 114 (58.77%) 67	53 / 87 (60.92%) 53	0 / 147 (0.00%) 0
Muscle pain (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data		

	collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[22] occurrences (all)	51 / 108 (47.22%) 51	38 / 84 (45.24%) 38	0 / 147 (0.00%) 0
Muscle pain (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[23] occurrences (all)	9 / 89 (10.11%) 9	11 / 67 (16.42%) 11	0 / 147 (0.00%) 0
Joint pain (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[24] occurrences (all)	41 / 103 (39.81%) 41	35 / 78 (44.87%) 35	0 / 147 (0.00%) 0
Joint pain (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[25] occurrences (all)	23 / 98 (23.47%) 23	25 / 72 (34.72%) 25	0 / 147 (0.00%) 0
Joint pain (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[26] occurrences (all)	22 / 94 (23.40%) 22	15 / 70 (21.43%) 15	0 / 147 (0.00%) 0
Joint pain (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed[27] occurrences (all)	4 / 89 (4.49%) 4	4 / 65 (6.15%) 4	0 / 147 (0.00%) 0
Respiratory, thoracic and mediastinal			

disorders			
Rhinitis allergic			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	1 / 147 (0.68%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Epistaxis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Listless			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Transfusion reaction			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	4 / 158 (2.53%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	4	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 158 (2.53%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	4	1	0
Convulsion			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Moyamoya disease			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Ocular icterus			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Periorbital oedema			
subjects affected / exposed	1 / 158 (0.63%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis allergic			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			

Hiatus hernia			
subjects affected / exposed	0 / 158 (0.00%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Pancreatic calcification			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Fatigue (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	78 / 118 (66.10%)	60 / 96 (62.50%)	0 / 147 (0.00%)
occurrences (all)	78	60	0

Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Swelling face			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Pain (Any)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	129 / 144 (89.58%)	95 / 111 (85.59%)	0 / 147 (0.00%)
occurrences (all)	129	95	0
Pain (Mild)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	108 / 132 (81.82%)	80 / 103 (77.67%)	0 / 147 (0.00%)
occurrences (all)	108	80	0
Pain (Moderate)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	64 / 113 (56.64%)	44 / 82 (53.66%)	0 / 147 (0.00%)
occurrences (all)	64	44	0
Pain (Severe)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	10 / 90 (11.11%)	11 / 69 (15.94%)	0 / 147 (0.00%)
occurrences (all)	10	11	0
Redness (Any)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[33]	22 / 93 (23.66%)	18 / 67 (26.87%)	0 / 147 (0.00%)
occurrences (all)	22	18	0
Redness (Mild)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	19 / 93 (20.43%)	10 / 66 (15.15%)	0 / 147 (0.00%)
occurrences (all)	19	10	0
Redness (Moderate)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	8 / 90 (8.89%)	9 / 64 (14.06%)	0 / 147 (0.00%)
occurrences (all)	8	9	0
Redness (Severe)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	1 / 87 (1.15%)	0 / 63 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Swelling (Any)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	53 / 108 (49.07%)	45 / 84 (53.57%)	0 / 147 (0.00%)
occurrences (all)	53	45	0
Swelling (Mild)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	38 / 101 (37.62%)	29 / 77 (37.66%)	0 / 147 (0.00%)
occurrences (all)	38	29	0
Swelling (Moderate)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[39]	26 / 100 (26.00%)	26 / 73 (35.62%)	0 / 147 (0.00%)
occurrences (all)	26	26	0
Swelling (Severe)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	1 / 87 (1.15%)	0 / 63 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Renal failure chronic			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	2 / 158 (1.27%)	2 / 140 (1.43%)	0 / 147 (0.00%)
occurrences (all)	2	3	0
Arthralgia			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	1 / 158 (0.63%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	1	1	0
Joint swelling			
subjects affected / exposed	0 / 158 (0.00%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	1 / 158 (0.63%)	1 / 140 (0.71%)	0 / 147 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 158 (1.27%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	2	0	0
Infection			

subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 158 (0.63%)	0 / 140 (0.00%)	0 / 147 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	1-Year Follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 87 (1.15%)		
Vascular disorders			
Vascular occlusion			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Injection site swelling			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Asthenia			

subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Injection site movement impairment			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Swelling			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Fever ≥38°C but ≤38.4°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 87 (0.00%)		
occurrences (all)	0		
Fever >38.4°C but ≤38.9°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 87 (0.00%)		
occurrences (all)	0		
Fever >38.9°C but ≤40.0°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 87 (0.00%)		
occurrences (all)	0		
Fever >40.0°C	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[4]	0 / 87 (0.00%)		
occurrences (all)	0		
Vomiting (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 87 (0.00%)		
occurrences (all)	0		
Vomiting (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 87 (0.00%)		
occurrences (all)	0		
Vomiting (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 87 (0.00%)		
occurrences (all)	0		
Vomiting (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 87 (0.00%)		
occurrences (all)	0		
Diarrhea (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 87 (0.00%)		
occurrences (all)	0		
Diarrhea (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[10]	0 / 87 (0.00%)		
occurrences (all)	0		
Diarrhea (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 87 (0.00%)		
occurrences (all)	0		
Diarrhea (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 87 (0.00%)		
occurrences (all)	0		
Headache (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 87 (0.00%)		
occurrences (all)	0		
Headache (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 87 (0.00%)		
occurrences (all)	0		
Headache (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 87 (0.00%)		
occurrences (all)	0		
Headache (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[16]	0 / 87 (0.00%)		
occurrences (all)	0		
Fatigue (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 87 (0.00%)		
occurrences (all)	0		
Fatigue (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 87 (0.00%)		
occurrences (all)	0		
Fatigue (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 87 (0.00%)		
occurrences (all)	0		
Muscle pain (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 87 (0.00%)		
occurrences (all)	0		
Muscle pain (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 87 (0.00%)		
occurrences (all)	0		
Muscle pain (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[22]	0 / 87 (0.00%)		
occurrences (all)	0		
Muscle pain (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 87 (0.00%)		
occurrences (all)	0		
Joint pain (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 87 (0.00%)		
occurrences (all)	0		
Joint pain (Mild)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 87 (0.00%)		
occurrences (all)	0		
Joint pain (Moderate)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 87 (0.00%)		
occurrences (all)	0		
Joint pain (Severe)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 87 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			

subjects affected / exposed occurrences (all) Productive cough subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Haemoptysis subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0		
Psychiatric disorders Listless subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0		
Injury, poisoning and procedural complications			

Transfusion reaction subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0		
Congenital, familial and genetic disorders Sickle cell anaemia with crisis subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Convulsion subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all) Moyamoya disease subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0		
Eye disorders Ocular icterus subjects affected / exposed occurrences (all) Periorbital oedema subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0		
Gastrointestinal disorders			

Hiatus hernia			
subjects affected / exposed	1 / 87 (1.15%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Gingival pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Oral pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Pancreatic calcification			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Fatigue (Any)	Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 87 (0.00%)		
occurrences (all)	0		

Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Swelling face			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Pain (Any)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 87 (0.00%)		
occurrences (all)	0		
Pain (Mild)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 87 (0.00%)		
occurrences (all)	0		
Pain (Moderate)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 87 (0.00%)		
occurrences (all)	0		
Pain (Severe)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 87 (0.00%)		
occurrences (all)	0		
Redness (Any)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[33]	0 / 87 (0.00%)		
occurrences (all)	0		
Redness (Mild)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 87 (0.00%)		
occurrences (all)	0		
Redness (Moderate)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 87 (0.00%)		
occurrences (all)	0		
Redness (Severe)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 87 (0.00%)		
occurrences (all)	0		
Swelling (Any)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 87 (0.00%)		
occurrences (all)	0		
Swelling (Mild)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 87 (0.00%)		
occurrences (all)	0		
Swelling (Moderate)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[39]	0 / 87 (0.00%)		
occurrences (all)	0		
Swelling (Severe)	Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 87 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Renal failure chronic			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Infection			

subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 87 (0.00%)		
occurrences (all)	0		

Notes:

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

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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported