Clinical trial results:
A Phase 3, Open-label Trial to Evaluate the Safety, Tolerability, and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine Followed by 23-valent Pneumococcal Polysaccharide Vaccine in Recipients of Allogeneic Hematopoietic Stem Cell Transplant Aged 2 Years and Older

Summary

EudraCT number	2009-012087-13
Trial protocol	BE DE SE FR NL ES CZ Outside EU/EEA
Global end of trial date	16 May 2013

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	02 August 2015

Trial information

Trial identification

Sponsor protocol code	B1851022 (6115A1-3003-WW)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00980655
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)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 October 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immune responses 1 month after 3 doses of 13-valent Pneumococcal Conjugate Vaccine (13vPnC) as measured by fold rises of serotype specific immunoglobulin G (IgG) geometric mean concentrations (GMCs) in subjects aged 2 Years and older.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on
Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 17
Country: Number of subjects enrolled	Belgium: 81
Country: Number of subjects enrolled	France: 46
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Spain: 26
Country: Number of subjects enrolled	Sweden: 35
Country: Number of subjects enrolled	Czech Republic: 7
Country: Number of subjects enrolled	Poland: 13
Country: Number of subjects enrolled	United States: 15
Country: Number of subjects enrolled	Canada: 6
Worldwide total number of subjects	247
EEA total number of subjects	226

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	34
Adolescents (12-17 years)	25
Adults (18-64 years)	168
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 61 and 190 subjects were enrolled in 13vPnC, 23vPS (Pediatric Subjects) and 13vPnC, 23vPS (Adult Subjects) respectively. Of these, 59 subjects in 13vPnC, 23vPS (Pediatric Subjects) and 188 subjects in 13vPnC, 23vPS (Adult Subjects) were treated.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC, 23vPS (Pediatric Subjects)

Arm description:

Pediatric subjects aged 2 to 17 years received 4 single doses of 13vPnC followed by a single dose of 23-valent pneumococcal polysaccharide vaccine (23vPS). 13vPnC Doses 1 to 3 were administered at 1-month intervals, 13vPnC Dose 4 was administered at 6 months after 13vPnC Dose 3, and 23vPS was administered 1 month after 13vPnC Dose 4.

Arm type	Experimental
Investigational medicinal product name	23vPS
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single 0.5 milliliter (mL) dose of 23vPS intramuscular injection administered 1 month after 13vPnC Dose 4.

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

Dosage and administration details:

Subjects received 4 single 0.5 mL doses of 13vPnC intramuscular injections. 13vPnC Doses 1 to 3 were administered at 1-month intervals, 13vPnC Dose 4 was administered at 6 months after 13vPnC Dose 3

Arm title	13vPnC, 23vPS (Adult Subjects)

Arm description:

Adult subjects aged 18 years and above received 4 single doses of 13vPnC followed by single dose of 23vPS. 13vPnC Doses 1 to 3 were administered at 1-month intervals, 13vPnC Dose 4 was administered at 6 months after 13vPnC Dose 3, and 23vPS was administered 1 month after 13vPnC Dose 4.

Arm type	Experimental
Investigational medicinal product name	23vPS
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:	
Single 0.5 mL dose of 23vPS intramuscular injection administered 1 month after 13vPnC Dose 4.	
Investigational medicinal product name	13vPnC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 single 0.5 mL doses of 13vPnC intramuscular injections. 13vPnC Doses 1 to 3 were administered at 1-month intervals, 13vPnC Dose 4 was administered at 6 months after 13vPnC Dose 3.

Number of subjects in period 1	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)
Started	59	188
Vaccinated 13vPnC Dose 1	59	188
Vaccinated 23vPS Dose	45	140
Vaccinated 13vPnC Dose 4	46	146
Vaccinated 13vPnC Dose 2	55	176
Vaccinated 13vPnC Dose 3	54	167
Completed	45	139
Not completed	14	49
Adverse Event	13	31
Death	-	7
Withdrawal by Subject	-	3
Protocol Violation	1	6
Unspecified	-	1
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC, 23vPS (Pediatric Subjects)
Reporting group description:	
Pediatric subjects aged 2 to 17 years received 4 single doses of 13vPnC followed by a single dose of 23-valent pneumococcal polysaccharide vaccine (23vPS). 13vPnC Doses 1 to 3 were administered at 1-month intervals, 13vPnC Dose 4 was administered at 6 months after 13vPnC Dose 3, and 23vPS was administered 1 month after 13vPnC Dose 4.	
Reporting group title	13vPnC, 23vPS (Adult Subjects)
Reporting group description:	
Adult subjects aged 18 years and above received 4 single doses of 13vPnC followed by single dose of 23vPS. 13vPnC Doses 1 to 3 were administered at 1-month intervals, 13vPnC Dose 4 was administered at 6 months after 13vPnC Dose 3, and 23vPS was administered 1 month after 13vPnC Dose 4.	

Reporting group values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	Total
Number of subjects	59	188	247
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	10.3	47.3	
standard deviation	± 4.41	± 12.39	-
Gender categorical Units: Subjects			
Female	26	74	100
Male	33	114	147

Serotype 4 (n=193)	23.85 (17.61 to 32.3)			
Serotype 5 (n=194)	2.99 (2.46 to 3.63)			
Serotype 6A (n=195)	5.35 (4.18 to 6.85)			
Serotype 6B (n=192)	5.18 (3.99 to 6.74)			
Serotype 7F (n=195)	10.28 (8.15 to 12.96)			
Serotype 9V (n=196)	5.76 (4.63 to 7.17)			
Serotype 14 (n=197)	4.95 (3.72 to 6.58)			
Serotype 18C (n=196)	8.22 (6.36 to 10.62)			
Serotype 19A (n=196)	3.9 (3.1 to 4.89)			
Serotype 19F (n=195)	6.73 (5.15 to 8.78)			
Serotype 23F (n=197)	8.01 (6.11 to 10.51)			

Notes:

[2] - N (number of subjects analyzed)=subjects evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 3 in Pediatric, Adult and All Subjects

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 3 in Pediatric, Adult and All Subjects

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) for pediatric, adult and all subjects are presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) CIs were evaluated. Geometric means were calculated using all subjects with available data for 1 month after 13vPnC Dose 3 blood draw. CI for GMC are back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population. Here, 'n' signifies all subjects who were evaluable for specified serotype for each treatment arm, respectively.

End point type	Secondary

End point timeframe:

1 month after 13vPnC Dose 3

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	49[3]	149[4]	198[5]	
Units: microgram per milliliter (mcg/mL)				
geometric mean (confidence interval 95%)				

Serotype 1 (n=49, 147, 196)	3.52 (2.38 to 5.19)	2.05 (1.53 to 2.76)	2.35 (1.84 to 2.99)	
Serotype 3 (n=49, 147, 196)	1.6 (1.13 to 2.26)	0.62 (0.49 to 0.79)	0.79 (0.64 to 0.97)	
Serotype 4 (n=49, 147, 196)	4.13 (2.68 to 6.36)	1.78 (1.35 to 2.34)	2.2 (1.73 to 2.78)	
Serotype 5 (n=48, 149, 197)	4.18 (2.95 to 5.91)	2 (1.6 to 2.51)	2.39 (1.97 to 2.91)	
Serotype 6A (n=49, 148, 197)	7.61 (5.16 to 11.23)	3.31 (2.53 to 4.33)	4.07 (3.25 to 5.11)	
Serotype 6B (n=48, 147, 195)	6.29 (3.88 to 10.19)	3 (2.25 to 3.98)	3.6 (2.81 to 4.61)	
Serotype 7F (n=48, 149, 197)	7.34 (5.12 to 10.53)	3.92 (3.08 to 5)	4.57 (3.72 to 5.61)	
Serotype 9V (n=49, 149, 198)	4.17 (3.01 to 5.98)	2.44 (1.93 to 3.1)	2.79 (2.29 to 3.4)	
Serotype 14 (n=49, 149, 198)	6.22 (4.03 to 9.61)	5.99 (4.35 to 8.26)	6.05 (4.65 to 7.86)	
Serotype 18C (n=49, 148, 197)	4.17 (2.9 to 5.98)	3.04 (2.37 to 3.91)	3.29 (2.67 to 4.05)	
Serotype 19A (n=49, 148, 197)	8.26 (5.86 to 11.65)	4.77 (3.77 to 6.04)	5.47 (4.49 to 6.67)	
Serotype 19F (n=49, 148, 197)	5.8 (3.8 to 8.84)	3.48 (2.69 to 4.5)	3.95 (3.17 to 4.93)	
Serotype 23F (n=49, 149, 198)	6.74 (4.12 to 11.05)	3.87 (2.85 to 5.26)	4.44 (3.42 to 5.77)	

Notes:

[3] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[4] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[5] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 4 in Pediatric, Adult and All Subjects

End point title	Geometric Mean Concentration (GMC) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 4 in Pediatric, Adult and All Subjects

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) for pediatric, adult and all subjects are presented. GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. Geometric means were calculated using all subjects with available data for 1 month after 13vPnC Dose 4 blood draw. CI for GMC are back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population. Here , 'n' signifies all subjects who were evaluable for specified serotype for each treatment arm, respectively.

End point type	Secondary

End point timeframe:

1 month after 13vPnC Dose 4

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	38[6]	124[7]	162[8]	
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=38, 123, 161)	8.75 (5.64 to 13.59)	4.67 (0.71 to 1.17)	5.41 (0.7 to 1.2)	
Serotype 3 (n=38, 123, 161)	1.23 (0.89 to 1.7)	0.91 (3.31 to 6.27)	0.97 (3.99 to 6.86)	
Serotype 4 (n=36, 124, 160)	8.41 (5.15 to 13.72)	4.56 (4.28 to 7.26)	5.23 (4.95 to 7.64)	
Serotype 5 (n=38, 122, 160)	8.43 (6.07 to 11.7)	5.57 (8.63 to 17)	6.15 (9.99 to 17.13)	
Serotype 6A (n=37, 122, 159)	16.33 (10.59 to 25.16)	12.23 (8.81 to 16.98)	13.08 (10.04 to 17.7)	
Serotype 6B (n=38, 124, 162)	18.13 (11.15 to 29.47)	12.13 (3.37 to 6.47)	13.33 (7 to 10.83)	
Serotype 7F (n=38, 124, 162)	10.37 (7.36 to 14.61)	8.26 (6.33 to 10.78)	8.71 (4.13 to 7.1)	
Serotype 9V (n=37, 124, 161)	7.78 (5.21 to 11.61)	5.09 (3.93 to 6.59)	5.61 (4.5 to 6.98)	
Serotype 14 (n=37, 124, 161)	16.04 (10.04 to 25.63)	12.24 (9.09 to 16.47)	13.02 (10.13 to 16.74)	
Serotype 18C (n=38, 122, 160)	6.54 (4.04 to 10.59)	6.69 (5.01 to 8.93)	6.65 (5.2 to 8.51)	
Serotype 19A (n=37, 124, 161)	16.94 (11.05 to 25.98)	12.99 (9.78 to 17.26)	13.81 (10.88 to 17.52)	
Serotype 19F (n=38, 123, 161)	19.96 (12.19 to 32.68)	13.69 (9.93 to 18.88)	14.96 (11.42 to 19.61)	
Serotype 23F (n=38, 123, 161)	16.65 (10.73 to 25.82)	12.68 (8.82 to 18.22)	13.52 (10.07 to 18.15)	

Notes:

[6] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[7] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[8] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 3 in Pediatric and Adult Subjects

End point title	Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 3 in Pediatric and Adult Subjects

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 3 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all students with available data from both before 13vPnC Dose 1 and after 13vPnC Dose 3 blood draws. Evaluable immunogenicity population. Here , 'n' signifies all subjects who were evaluable for specified serotype for each treatment arm, respectively.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 1 (pre-vaccination), 1 month after 13vPnC Dose 3

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[9]	148[10]		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 1 (n=48, 143)	27.64 (16.75 to 45.62)	15.54 (11.2 to 21.56)		
Serotype 3 (n=48, 144)	7.58 (4.74 to 12.13)	4.43 (3.35 to 5.88)		
Serotype 4 (n=49, 144)	40.83 (23.84 to 69.95)	19.86 (13.83 to 28.52)		
Serotype 5 (n=47, 147)	4.11 (2.86 to 5.9)	2.7 (2.15 to 3.39)		
Serotype 6A (n=48, 147)	7.49 (4.79 to 11.72)	4.79 (3.57 to 6.44)		
Serotype 6B (n=47, 145)	6.02 (3.79 to 9.55)	4.94 (3.6 to 6.77)		
Serotype 7F (n=48, 147)	14.65 (9.63 to 22.28)	9.15 (6.95 to 12.05)		
Serotype 9V (n=48, 148)	7.64 (5.4 to 10.82)	5.26 (4.02 to 6.87)		
Serotype 14 (n=49, 148)	5.01 (2.83 to 8.86)	4.92 (3.53 to 6.87)		
Serotype 18C (n=49, 147)	12.59 (7.84 to 20.21)	7.13 (5.27 to 9.65)		
Serotype 19A (n=49, 147)	5.04 (3.38 to 7.51)	3.58 (2.72 to 4.7)		
Serotype 19F (n=49, 146)	7.66 (4.67 to 12.57)	6.44 (4.69 to 8.85)		
Serotype 23F (n=49, 148)	9.73 (5.79 to 16.34)	7.52 (5.46 to 10.35)		

Notes:

[9] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[10] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 4 in Pediatric, Adult and All Subjects

End point title	Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 4 in Pediatric, Adult and All Subjects

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 4 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t

distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both before 13vPnC Dose 1 and after 13vPnC Dose 4 blood draws. Evaluable immunogenicity population. Here, 'n' signifies all subjects who were evaluable for specified serotype for each treatment arm, respectively.

End point type	Secondary

End point timeframe:

Before 13vPnC Dose 1 (pre-vaccination), 1 month after 13vPnC Dose 4

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	38[11]	123[12]	161[13]	
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 1 (n=37, 120, 157)	70.66 (39.2 to 127.36)	35.81 (25.06 to 51.18)	42.03 (30.94 to 57.11)	
Serotype 3 (n=37, 120, 157)	5.88 (3.25 to 10.61)	6.41 (4.74 to 8.66)	6.28 (4.81 to 8.19)	
Serotype 4 (n=36, 121, 157)	90.31 (48.05 to 169.77)	47.47 (32.09 to 70.22)	55.02 (39.39 to 76.85)	
Serotype 5 (n=37, 119, 156)	7.76 (4.81 to 12.51)	7.29 (5.32 to 9.99)	7.4 (5.69 to 9.63)	
Serotype 6A (n=36, 121, 157)	15.62 (9.63 to 25.34)	17.02 (11.95 to 24.23)	16.7 (12.47 to 22.34)	
Serotype 6B (n=37, 122, 159)	16.9 (9.76 to 29.25)	20.09 (13.94 to 28.94)	19.29 (14.22 to 26.18)	
Serotype 7F (n=38, 123, 161)	19.18 (11.75 to 31.33)	18.69 (13.7 to 25.5)	18.81 (14.48 to 24.43)	
Serotype 9V (n=36, 122, 158)	14.9 (9.55 to 23.25)	11.13 (8.27 to 14.99)	11.9 (9.27 to 15.27)	
Serotype 14 (n=37, 123, 160)	12.61 (6.47 to 24.56)	9.69 (6.8 to 13.8)	10.3 (7.55 to 14.03)	
Serotype 18C (n=38, 121, 159)	21.22 (12.05 to 37.36)	14.4 (10.17 to 20.41)	15.8 (11.76 to 21.24)	
Serotype 19A (n=37, 123, 160)	11.46 (7.22 to 18.2)	9.52 (6.9 to 13.12)	9.94 (7.61 to 12.98)	
Serotype 19F (n=38, 120, 158)	29.31 (16.63 to 51.64)	25.63 (17.56 to 37.43)	26.47 (19.31 to 36.29)	
Serotype 23F (n=38, 122, 160)	25.37 (14.69 to 43.83)	23.02 (15.63 to 33.92)	23.56 (17.11 to 32.45)	

Notes:

[11] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[12] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[13] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 3 to 1 Month After 13vPnC Dose 4 in Pediatric, Adult and All Subjects

End point title	Geometric Mean Fold Rise (GMFR) for Serotype-specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month

	After 13vPnC Dose 3 to 1 Month After 13vPnC Dose 4 in Pediatric, Adult and All Subjects

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 3 to 1 month after 13vPnC Dose 4 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both after 13vPnC Dose 3 and after 13vPnC Dose 4 blood draws. Evaluable immunogenicity population. Here, 'n' signifies all subjects who were evaluable for specified serotype for each treatment arm, respectively.

End point type	Secondary

End point timeframe:

1 month after 13vPnC Dose 3, 1 month after 13vPnC Dose 4

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	37[14]	121[15]	157[16]	
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 1 (n=37, 119, 156)	2.8 (1.99 to 3.95)	2.16 (1.65 to 2.82)	2.3 (1.85 to 2.86)	
Serotype 3 (n=37, 119, 156)	0.88 (0.64 to 1.22)	1.32 (1.07 to 1.62)	1.2 (1.01 to 1.43)	
Serotype 4 (n=35, 121, 156)	2.19 (1.51 to 3.19)	2.32 (1.88 to 2.86)	2.29 (1.91 to 2.74)	
Serotype 5 (n=37, 119, 156)	2.25 (1.74 to 2.93)	2.43 (1.94 to 3.06)	2.39 (1.99 to 2.87)	
Serotype 6A (n=36, 119, 155)	2.36 (1.87 to 2.99)	3.06 (2.35 to 3.98)	2.88 (2.34 to 3.55)	
Serotype 6B (n=37, 120, 157)	2.96 (2.09 to 4.19)	3.1 (2.44 to 3.95)	3.07 (2.51 to 3.75)	
Serotype 7F (n=36, 121, 157)	1.51 (1.08 to 2.11)	1.83 (1.47 to 2.29)	1.75 (1.46 to 2.11)	
Serotype 9V (n=36, 121, 157)	2.08 (1.43 to 3.03)	1.82 (1.48 to 2.23)	1.88 (1.57 to 2.24)	
Serotype 14 (n=36, 121, 157)	2.5 (1.65 to 3.8)	1.68 (1.32 to 2.13)	1.84 (1.5 to 2.26)	
Serotype 18C (n=37, 118, 155)	1.64 (1.24 to 2.16)	1.87 (1.54 to 2.28)	1.81 (1.54 to 2.13)	
Serotype 19A (n=36, 121, 157)	2.25 (1.6 to 3.17)	2.33 (1.91 to 2.85)	2.31 (1.95 to 2.74)	
Serotype 19F (n=37, 120, 157)	3.5 (2.15 to 5.68)	3.65 (2.9 to 4.59)	3.61 (2.94 to 4.44)	
Serotype 23F (n=37, 120, 157)	2.49 (1.72 to 3.61)	2.59 (2.04 to 3.3)	2.57 (2.1 to 3.14)	

Notes:

[14] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[15] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

[16] - N (number of subjects analyzed) signifies all subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 1

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 1

End point description:

Specific local reactions were prompted for each day, and reported using an electronic diary. Redness and Swelling were scaled as Any (redness present or swelling present); Mild (0.5 to 2.0 centimeters [cm] for subjects aged 2 to less than [<]12 years and 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 2 to <12 years and 5.5 to 10.0 cm for subjects aged >=12 years); Severe (greater than [>] 7.0 cm for subjects aged 2 to <12 years and >10.0 cm for subjects aged >=12 years). Pain at injection site was scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Population analysed was the safety population. Here, 'n' signifies subjects with known values for specified local reaction. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 14 days after 13vPnC Dose 1

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	52[17]	171[18]	223[19]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: any (n = 38, 130, 168)	21.1 (9.6 to 37.3)	11.5 (6.6 to 18.3)	13.7 (8.9 to 19.8)	
Redness: mild (n = 38, 130, 168)	15.8 (0 to 9.5)	10.8 (6 to 17.4)	11.9 (7.4 to 17.8)	
Redness: moderate (n = 37, 128, 165)	10.8 (12.7 to 41.2)	1.6 (0.2 to 5.5)	3.6 (1.3 to 7.7)	
Redness: severe (n = 37, 128, 165)	0 (2.9 to 24.2)	0 (0 to 2.8)	0 (0 to 2.2)	
Swelling: any (n = 40, 130, 170)	25 (9.3 to 36.5)	11.5 (6.6 to 18.3)	14.7 (9.7 to 20.9)	
Swelling: mild (n = 39, 130, 169)	10.3 (0 to 9.5)	10.8 (6 to 17.4)	10.7 (6.4 to 16.3)	
Swelling: moderate (n = 39, 128, 167)	20.5 (64.7 to 88.7)	0.8 (0 to 4.3)	5.4 (2.5 to 10)	
Swelling: severe (n = 37, 128, 165)	0 (53.7 to 81.3)	0.8 (0 to 4.3)	0.6 (0 to 3.3)	
Pain: any (n = 51, 171, 222)	78.4 (29.8 to 61.3)	73.1 (65.8 to 79.6)	74.3 (68.1 to 79.9)	
Pain: mild (n = 48, 169, 217)	68.8 (0.7 to 18.2)	69.8 (62.3 to 76.6)	69.6 (63 to 75.6)	
Pain: moderate (n = 42, 138, 180)	45.2 (9.6 to 37.3)	22.5 (15.8 to 30.3)	27.8 (21.4 to 34.9)	
Pain: severe (n = 37, 129, 166)	5.4 (0.7 to 18.2)	2.3 (0.5 to 6.6)	3 (1 to 6.9)	

Notes:

[17] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[18] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[19] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 2

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 2

End point description:

Specific local reactions were prompted for each day, and reported using an electronic diary. Redness and Swelling were scaled as Any (redness present or swelling present); Mild (0.5 to 2.0 cm for subjects aged 2 to <12 years and 2.5 to 5.0 cm for subjects aged >=12 years); Moderate (2.5 to 7.0 cm for subjects aged 2 to <12 years and 5.5 to 10.0 cm for subjects aged >=12 years); Severe >7.0 cm for subjects aged 2 to <12 years and >10.0 cm for subjects aged >=12 years). Pain at injection site was scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Population analysed was the safety population. Here, 'n' signifies subjects with known values for specified local reaction. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 14 days after 13vPnC Dose 2

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	41[20]	157[21]	198[22]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: any (n = 28, 109, 137)	42.9 (24.5 to 62.8)	16.5 (10.1 to 24.8)	21.9 (15.3 to 29.8)	
Redness: mild (n = 26, 108, 134)	34.6 (17.2 to 55.7)	15.7 (9.4 to 24)	19.4 (13.1 to 27.1)	
Redness: moderate (n = 26, 103, 129)	26.9 (11.6 to 47.8)	1.9 (0.2 to 6.8)	7 (3.2 to 12.8)	
Redness: severe (n = 24, 103, 127)	4.2 (0.1 to 21.1)	1 (0 to 5.3)	1.6 (0.2 to 5.6)	
Swelling: any (n = 28, 105, 133)	35.7 (18.6 to 55.9)	14.3 (8.2 to 22.5)	18.8 (12.5 to 26.5)	
Swelling: mild (n = 26, 105, 131)	15.4 (4.4 to 34.9)	14.3 (8.2 to 22.5)	14.5 (9 to 21.7)	
Swelling: moderate (n = 26, 102, 128)	26.9 (11.6 to 47.8)	0 (0 to 3.6)	5.5 (2.2 to 10.9)	
Swelling: severe (n = 24, 102, 126)	0 (0 to 14.2)	0 (0 to 3.6)	0 (0 to 2.9)	
Pain: any (n = 40, 154, 194)	77.5 (61.5 to 89.2)	74.7 (67 to 81.3)	75.3 (68.6 to 81.2)	
Pain: mild (n = 36, 148, 184)	66.7 (49 to 81.4)	70.9 (62.9 to 78.1)	70.1 (62.9 to 76.6)	
Pain: moderate (n = 32, 116, 148)	53.1 (34.7 to 70.9)	27.6 (19.7 to 36.7)	33.1 (25.6 to 41.3)	
Pain: severe (n = 27, 104, 131)	14.8 (4.2 to 33.7)	1.9 (0.2 to 6.8)	4.6 (1.7 to 9.7)	

Notes:

[20] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[21] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[22] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 3

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 3

End point description:

Specific local reactions were prompted for each day, and reported using an electronic diary. Redness and Swelling were scaled as Any (redness present or swelling present); Mild (0.5 to 2.0 cm for subjects aged 2 to <12 years and 2.5 to 5.0 cm for subjects aged >=12 years); Moderate (2.5 to 7.0 cm for subjects aged 2 to <12 years and 5.5 to 10.0 cm for subjects aged >=12 years); Severe >7.0 cm for subjects aged 2 to <12 years and >10.0 cm for subjects aged >=12 years). Pain at injection site was scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Population analysed was the safety population. Here, 'n' signifies subjects with known values for specified local reaction. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 14 days after 13vPnC Dose 3

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	37[23]	138[24]	175[25]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: any (n = 25, 95, 120)	32 (45.25 to 80.8)	9.5 (4.4 to 17.2)	14.2 (8.5 to 21.7)	
Redness: mild (n = 24, 94, 118)	20.8 (22.2 to 56.4)	8.5 (3.7 to 16.1)	11 (6 to 18.1)	
Redness: moderate (n = 24, 93, 117)	20.8 (14.9 to 53.5)	1.1 (0 to 5.8)	5.1 (1.9 to 10.8)	
Redness: severe (n = 23, 93, 116)	4.3 (7.1 to 42.2)	1.1 (0 to 5.8)	1.7 (0.2 to 6.1)	
Swelling: any (n = 28, 93, 121)	35.7 (7.1 to 42.2)	8.6 (3.8 to 16.2)	14.9 (9.1 to 22.5)	
Swelling: mild (n = 27, 93, 120)	25.9 (0.1 to 21.9)	8.6 (3.8 to 16.2)	12.5 (7.2 to 19.8)	
Swelling: moderate (n = 25, 92, 117)	20 (18.6 to 55.9)	0 (0 to 3.9)	4.3 (1.4 to 9.7)	
Swelling: severe (n = 23, 92, 115)	4.3 (11.1 to 46.3)	0 (0 to 3.9)	0.9 (0 to 4.7)	
Pain: any (n = 37, 138, 175)	70.3 (6.8 to 40.7)	73.2 (65 to 80.4)	72.6 (65.3 to 79)	
Pain: mild (n = 31, 132, 163)	64.5 (0.1 to 21.9)	67.4 (58.7 to 75.3)	66.9 (59.1 to 74)	
Pain: moderate (n = 34, 107, 141)	38.2 (53 to 84.1)	27.1 (19 to 36.6)	29.8 (22.4 to 38.1)	
Pain: severe (n = 24, 93, 117)	8.3 (1 to 27)	3.2 (0.7 to 9.1)	4.3 (1.4 to 9.7)	

Notes:

[23] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[24] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

Pain: moderate (n = 24, 85, 109)	62.5 (40.6 to 81.2)	31.8 (22.1 to 42.8)	38.5 (29.4 to 48.3)	
Pain: severe (n = 16, 74, 90)	12.5 (1.6 to 38.3)	5.4 (1.5 to 13.3)	6.7 (2.5 to 13.9)	

Notes:

[26] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[27] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

[28] - N (number of subjects analyzed) signifies subjects with known values for any local reaction.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 1

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 1

End point description:

Specific systemic events (fever >=38 degrees Celsius [C], fatigue, headache, vomiting, diarrhea, muscle pain, joint pain and use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any (symptom present); Mild (did not interfere with activity); Moderate (some interference with activity); 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. Here, 'n' signifies subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 14 days after 13vPnC Dose 1

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51[29]	172[30]	223[31]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38 degrees C (n = 39, 130, 169)	12.8 (4.3 to 27.4)	6.2 (2.7 to 11.8)	7.7 (4.2 to 12.8)	
Fever: >=38, <38.5 degrees C (n = 37, 130, 167)	5.4 (0.7 to 18.2)	6.2 (2.7 to 11.8)	6 (2.9 to 10.7)	
Fever: >=38.5, <39 degrees C (n = 37, 128, 165)	5.4 (0.7 to 18.2)	0 (0 to 2.8)	1.2 (0.1 to 4.3)	
Fever: >=39, =<40 degrees C (n = 39, 128, 167)	7.7 (1.6 to 20.9)	0 (0 to 2.8)	1.8 (0.4 to 5.2)	
Fever: >40 degrees C (n = 37, 128, 165)	0 (0 to 9.5)	0 (0 to 2.8)	0 (0 to 2.2)	
Fatigue: Any (n = 45, 159, 204)	53.3 (37.9 to 68.3)	59.7 (51.7 to 67.4)	58.3 (51.2 to 65.2)	
Fatigue: Mild (n = 41, 149, 190)	36.6 (22.1 to 53.1)	49 (40.7 to 57.3)	46.3 (39.1 to 53.7)	
Fatigue: Moderate (n = 44, 148, 192)	36.4 (22.4 to 52.2)	35.8 (28.1 to 44.1)	35.9 (29.2 to 43.2)	
Fatigue: Severe (n = 37, 136, 173)	10.8 (3 to 25.4)	11.8 (6.9 to 18.4)	11.6 (7.2 to 17.3)	

Headache: Any (n = 42, 147, 189)	45.2 (29.8 to 61.3)	44.2 (36 to 52.6)	44.4 (37.2 to 51.8)	
Headache: Mild (n = 41, 145, 186)	39 (24.2 to 55.5)	37.9 (30 to 46.4)	38.2 (31.2 to 45.6)	
Headache: Moderate (n = 40, 134, 174)	20 (9.1 to 35.6)	17.2 (11.2 to 24.6)	17.8 (12.4 to 24.3)	
Headache: Severe (n = 37, 130, 167)	2.7 (0.1 to 14.2)	2.3 (0.5 to 6.6)	2.4 (0.7 to 6)	
Vomiting: Any (n = 39, 134, 173)	20.5 (9.3 to 36.5)	20.9 (14.4 to 28.8)	20.8 (15 to 27.6)	
Vomiting: Mild (n = 38, 134, 172)	18.4 (7.7 to 34.3)	17.9 (11.8 to 25.5)	18 (12.6 to 24.6)	
Vomiting: Moderate (n = 38, 128, 166)	2.6 (0.1 to 13.8)	3.9 (1.3 to 8.9)	3.6 (1.3 to 7.7)	
Vomiting: Severe (n = 37, 128, 165)	5.4 (0.7 to 18.2)	0 (0 to 2.8)	1.2 (0.1 to 4.3)	
Diarrhea: Any (n = 44, 145, 189)	31.8 (18.6 to 47.6)	35.9 (28.1 to 44.2)	34.9 (28.1 to 42.2)	
Diarrhea: Mild (n = 44, 142, 186)	31.8 (18.6 to 47.6)	33.8 (26.1 to 42.2)	33.3 (26.6 to 40.6)	
Diarrhea: Moderate (n = 38, 133, 171)	5.3 (0.6 to 17.7)	9 (4.7 to 15.2)	8.2 (4.5 to 13.4)	
Diarrhea: Severe (n = 37, 131, 168)	0 (0 to 9.5)	3.8 (1.3 to 8.7)	3 (1 to 6.8)	
Muscle Pain: Any (n = 47, 154, 201)	55.3 (40.1 to 69.8)	50 (41.8 to 58.2)	51.2 (44.1 to 58.3)	
Muscle Pain: Mild (n = 43, 148, 191)	46.5 (31.2 to 62.3)	42.6 (34.5 to 51)	43.5 (36.3 to 50.8)	
Muscle Pain: Moderate (n = 44, 139, 183)	36.4 (22.4 to 52.2)	21.6 (15.1 to 29.4)	25.1 (19 to 32.1)	
Muscle Pain: Severe (n = 37, 131, 168)	5.4 (0.7 to 18.2)	5.3 (2.2 to 10.7)	5.4 (2.5 to 9.9)	
Joint Pain: Any (n = 38, 143, 181)	26.3 (13.4 to 43.1)	26.6 (19.5 to 34.6)	26.5 (20.2 to 33.6)	
Joint Pain: Mild (n = 37, 139, 176)	18.9 (8 to 35.2)	19.4 (13.2 to 27)	19.3 (13.8 to 25.9)	
Joint Pain: Moderate (n = 38, 137, 175)	15.8 (6 to 31.3)	14.6 (9.2 to 21.6)	14.9 (9.9 to 21)	
Joint Pain: Severe (n = 37, 130, 167)	2.7 (0.1 to 14.2)	3.1 (0.8 to 7.7)	3 (1 to 6.8)	
Use of Medication to Treat Pain (n= 40, 136, 176)	25 (12.7 to 41.2)	13.2 (8 to 20.1)	15.9 (10.8 to 22.2)	
Use of Medication to Treat Fever (n= 41, 133, 174)	24.4 (12.4 to 40.3)	14.3 (8.8 to 21.4)	16.7 (11.5 to 23.1)	

Notes:

[29] - N signifies subjects with known values for any systemic event.

[30] - N signifies subjects with known values for any systemic event.

[31] - N signifies subjects with known values for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 2

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 2

End point description:

Specific systemic events (fever >=38 degrees Celsius [C], fatigue, headache, vomiting, diarrhea, muscle pain, joint pain and use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any (symptom

present); Mild (did not interfere with activity); Moderate (some interference with activity); 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. Here, 'n' signifies subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

End point type	Other pre-specified
End point timeframe: Within 14 days after 13vPnC Dose 2	

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	45[32]	146[33]	191	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38 degrees C (n = 26, 105, 131)	23.1 (9 to 43.6)	6.7 (2.7 to 13.3)	27.5 (5.4 to 16.4)	
Fever: >=38, <38.5 degrees C (n = 26, 105, 131)	19.2 (6.6 to 39.4)	5.7 (2.1 to 12)	9.7 (4.3 to 14.5)	
Fever: >=38.5, <39 degrees C (n = 24, 102, 126)	8.3 (1 to 27)	1 (0 to 5.3)	1.6 (0.5 to 6.8)	
Fever: >=39, =<40 degrees C (n = 24, 102, 126)	8.3 (1 to 27)	1 (0 to 5.3)	45 (0.5 to 6.8)	
Fever: >40 degrees C (n = 24, 102, 126)	0 (0 to 14.2)	0 (0 to 3.6)	36 (0 to 2.9)	
Fatigue: Any (n = 38, 133, 171)	60.5 (43.4 to 76)	56.4 (47.5 to 65)	28 (49.5 to 64.8)	
Fatigue: Mild (n = 31, 125, 156)	45.2 (27.3 to 64)	39.2 (30.6 to 48.3)	6.1 (32.6 to 48.5)	
Fatigue: Moderate (n = 33, 122, 155)	45.5 (28.1 to 63.6)	37.7 (29.1 to 46.9)	25.2 (31.6 to 47.5)	
Fatigue: Severe (n = 24, 107, 131)	12.5 (2.7 to 32.4)	9.3 (4.6 to 16.5)	21.1 (5.4 to 16.4)	
Headache: Any (n = 31, 121,152)	32.3 (16.7 to 51.4)	35.5 (27 to 44.8)	14.7 (27.3 to 43)	
Headache: Mild (n = 30, 117, 147)	30 (14.7 to 49.4)	29.9 (21.8 to 39.1)	2.3 (22.7 to 38)	
Headache: Moderate (n = 26, 110, 136)	7.7 (0.9 to 25.1)	16.4 (10 to 24.6)	11.3 (9.2 to 21.8)	
Headache: Severe (n = 24, 104, 128)	0 (0 to 14.2)	1.9 (0.2 to 6.8)	14.9 (0.2 to 5.5)	
Vomiting: Any (n = 28, 107, 135)	21.4 (8.3 to 41)	13.1 (7.3 to 21)	9.9 (9.3 to 21.9)	
Vomiting: Mild (n = 27, 107, 134)	18.5 (6.3 to 38.1)	10.3 (5.2 to 17.7)	8.4 (7 to 18.7)	
Vomiting: Moderate (n = 28, 103, 131)	14.3 (4 to 32.7)	4.9 (1.6 to 11)	2.4 (3.2 to 12.6)	
Vomiting: Severe (n = 24, 102, 126)	0 (0 to 14.2)	1 (0 to 5.3)	2.4 (0 to 4.3)	
Diarrhea: Any (n = 29, 121, 150)	31 (15.3 to 50.8)	28.9 (21 to 37.9)	0 (22.2 to 37.3)	
Diarrhea: Mild (n = 29, 120, 149)	31 (15.3 to 50.8)	26.7 (19 to 35.5)	57.3 (20.5 to 35.4)	
Diarrhea: Moderate (n = 25, 109, 134)	8 (1 to 26)	10.1 (5.1 to 17.3)	40.4 (5.3 to 16)	

Diarrhea: Severe (n = 24, 103, 127)	0 (0 to 14.2)	1.9 (0.2 to 6.8)	39.4 (0.2 to 5.6)	
Muscle Pain: Any (n = 36, 124, 160)	44.4 (27.9 to 61.9)	45.2 (36.2 to 54.3)	9.9 (37.1 to 53.1)	
Muscle Pain: Mild (n = 32, 118, 150)	31.3 (16.1 to 50)	37.3 (28.6 to 46.7)	34.9 (28.3 to 44.2)	
Muscle Pain: Moderate (n = 32, 111, 143)	37.5 (21.1 to 56.3)	25.2 (17.5 to 34.4)	29.9 (20.8 to 36.1)	
Muscle Pain: Severe (n = 25, 106, 131)	8 (1 to 26)	5.7 (2.1 to 11.9)	14.7 (2.7 to 11.7)	
Joint Pain: Any (n = 31, 116, 147)	32.3 (16.7 to 51.4)	23.3 (15.9 to 32)	1.6 (18.4 to 33)	
Joint Pain: Mild (n = 27, 115, 142)	18.5 (6.3 to 38.1)	21.7 (14.6 to 30.4)	14.8 (14.7 to 28.8)	
Joint Pain: Moderate (n = 30, 106, 136)	30 (14.7 to 49.4)	10.4 (5.3 to 17.8)	11.9 (9.2 to 21.8)	
Joint Pain: Severe (n = 25, 104, 129)	4 (0.1 to 20.4)	1.9 (0.2 to 6.8)	6.9 (0.5 to 6.6)	
Use of Medication to Treat Pain (n= 28, 105, 133)	25 (10.7 to 44.9)	7.6 (3.3 to 14.5)	0.8 (6.5 to 17.9)	
Use of Medication to Treat Fever (n= 27, 107, 134)	33.3 (16.5 to 54)	10.3 (5.2 to 17.7)	29.3 (9.4 to 22.1)	

Notes:

[32] - N signifies subjects with known values for any systemic event.

[33] - N signifies subjects with known values for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 3

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 3

End point description:

Specific systemic events (fever >=38 degrees Celsius [C], fatigue, headache, vomiting, diarrhea, muscle pain, joint pain and use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any (symptom present); Mild (did not interfere with activity); Moderate (some interference with activity); 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. Here, 'n' signifies subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 14 days after 13vPnC Dose 3

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	42[34]	136[35]	178[36]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38 degrees C (n = 27, 93, 120)	14.8 (0.1 to 21.1)	4.3 (1.2 to 10.6)	6.7 (2.9 to 12.7)	

Fever: >=38, <38.5 degrees C (n = 26, 93, 119)	11.5 (0.1 to 21.1)	3.2 (0.7 to 9.1)	5 (1.9 to 10.7)	
Fever: >=38.5, <39 degrees C (n = 24, 93, 117)	4.2 (0 to 14.8)	3.2 (0.7 to 9.1)	3.4 (0.9 to 8.5)	
Fever: >=39, =<40 degrees C (n = 24, 92, 116)	4.2 (31.4 to 66)	1.1 (0 to 5.9)	1.7 (0.2 to 6.1)	
Fever: >40 degrees C (n = 23, 92, 115)	0 (23.7 to 59.4)	0 (0 to 3.9)	0 (0 to 3.2)	
Fatigue: Any (n = 35, 122, 157)	48.6 (17.3 to 52.8)	49.2 (40 to 58.4)	49 (41 to 57.1)	
Fatigue: Mild (n = 32, 116, 148)	40.6 (0.1 to 21.1)	38.8 (29.9 to 48.3)	39.2 (31.3 to 47.5)	
Fatigue: Moderate (n = 30, 107, 137)	33.3 (4.2 to 33.7)	29.9 (21.4 to 39.5)	30.7 (23.1 to 39.1)	
Fatigue: Severe (n = 24, 96, 120)	4.2 (2.4 to 30.2)	7.3 (3 to 14.4)	6.7 (2.9 to 12.7)	
Headache: Any (n = 32, 110,142)	37.5 (21.1 to 56.3)	37.3 (28.2 to 47)	37.3 (29.4 to 45.8)	
Headache: Mild (n = 30, 108, 138)	30 (14.7 to 49.4)	32.4 (23.7 to 42.1)	31.9 (24.2 to 40.4)	
Headache: Moderate (n = 27, 95, 122)	22.2 (8.6 to 42.3)	15.8 (9.1 to 24.7)	17.2 (11 to 25.1)	
Headache: Severe (n = 25, 94, 119)	8 (1 to 26)	2.1 (0.3 to 7.5)	3.4 (0.9 to 8.4)	
Vomiting: Any (n = 25, 95, 120)	8 (1 to 26)	11.6 (5.9 to 19.8)	10.8 (5.9 to 17.8)	
Vomiting: Mild (n = 24, 95, 119)	4.2 (0.1 to 21.1)	5.3 (1.7 to 11.9)	5 (1.9 to 10.7)	
Vomiting: Moderate (n = 24, 93, 117)	4.2 (0.1 to 21.1)	7.5 (3.1 to 14.9)	6.8 (3 to 13)	
Vomiting: Severe (n = 23, 92, 115)	0 (0 to 14.8)	0 (0 to 3.9)	0 (0 to 3.2)	
Diarrhea: Any (n = 26, 104, 130)	15.4 (4.4 to 34.9)	25 (17 to 34.4)	23.1 (16.1 to 31.3)	
Diarrhea: Mild (n = 26, 102, 128)	15.4 (4.4 to 34.9)	21.6 (14 to 30.8)	20.3 (13.7 to 28.3)	
Diarrhea: Moderate (n = 24, 95, 119)	4.2 (0.1 to 21.1)	5.3 (1.7 to 11.9)	5 (1.9 to 10.7)	
Diarrhea: Severe (n = 23, 94, 117)	0 (0 to 14.8)	2.1 (0.3 to 7.5)	1.7 (0.2 to 6)	
Muscle Pain: Any (n = 35, 117, 152)	45.7 (28.8 to 63.4)	38.5 (29.6 to 47.9)	40.1 (32.3 to 48.4)	
Muscle Pain: Mild (n = 30, 112, 142)	33.3 (17.3 to 52.8)	33 (24.4 to 42.6)	33.1 (25.4 to 41.5)	
Muscle Pain: Moderate (n = 31, 101, 132)	32.3 (16.7 to 51.4)	16.8 (10.1 to 25.6)	20.5 (13.9 to 28.3)	
Muscle Pain: Severe (n = 24, 94, 118)	4.2 (0.1 to 21.1)	3.2 (0.7 to 9)	3.4 (0.9 to 8.5)	
Joint Pain: Any (n = 28, 104, 132)	25 (10.7 to 44.9)	20.2 (13 to 29.2)	21.2 (14.6 to 29.2)	
Joint Pain: Mild (n = 26, 102, 128)	19.2 (6.6 to 39.4)	17.6 (10.8 to 26.4)	18 (11.7 to 25.7)	
Joint Pain: Moderate (n = 27, 95, 122)	18.5 (6.3 to 38.1)	8.4 (3.7 to 15.9)	10.7 (5.8 to 17.5)	
Joint Pain: Severe (n = 25, 94, 119)	8 (1 to 26)	2.1 (0.3 to 7.5)	3.4 (0.9 to 8.4)	
Use of Medication to Treat Pain (n= 28, 97, 125)	21.4 (8.3 to 41)	12.4 (6.6 to 20.6)	14.4 (8.8 to 21.8)	
Use of Medication to Treat Fever (n= 30, 101, 131)	26.7 (12.3 to 45.9)	15.8 (9.3 to 24.4)	18.3 (12.1 to 26)	

Notes:

[34] - N signifies subjects with known values for any systemic event.

[35] - N signifies subjects with known values for any systemic event.

[36] - N signifies subjects with known values for any systemic event.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 4

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Systemic Events: 13vPnC Dose 4

End point description:

Specific systemic events (fever >=38 degrees Celsius [C], fatigue, headache, vomiting, diarrhea, muscle pain, joint pain and use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any (symptom present); Mild (did not interfere with activity); Moderate (some interference with activity); 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. Here, 'n' signifies subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

End point type	Other pre-specified

End point timeframe:

Within 14 days after 13vPnC Dose 4

End point values	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)	13vPnC, 23vPS (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	32[37]	116[38]	148[39]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38 degrees C (n= 18, 78, 96)	27.8 (9.7 to 53.5)	15.4 (8.2 to 25.3)	17.7 (10.7 to 26.8)	
Fever: >=38, <38.5 degrees C (n = 16, 76, 92)	12.5 (1.6 to 38.3)	13.2 (6.5 to 22.9)	13 (6.9 to 21.7)	
Fever: >=38.5, <39 degrees C (n = 17, 73, 90)	17.6 (3.8 to 43.4)	2.7 (0.3 to 9.5)	5.6 (1.8 to 12.5)	
Fever: >=39, =<40 degrees C (n = 15, 72, 87)	0 (0 to 21.8)	2.8 (0.3 to 9.7)	2.3 (0.3 to 8.1)	
Fever: >40 degrees C (n = 15, 71, 86)	0 (0 to 21.8)	0 (0 to 5.1)	0 (0 to 4.2)	
Fatigue: Any (n = 28, 100, 128)	67.9 (47.6 to 84.1)	67 (56.9 to 76.1)	67.2 (58.3 to 75.2)	
Fatigue: Mild (n = 26, 95, 121)	61.5 (40.6 to 79.8)	54.7 (44.2 to 65)	56.2 (46.9 to 65.2)	
Fatigue: Moderate (n = 20, 86, 106)	45 (23.1 to 68.5)	45.3 (34.6 to 56.5)	45.3 (35.6 to 55.2)	
Fatigue: Severe (n = 16, 77, 93)	12.5 (1.6 to 38.3)	13 (6.4 to 22.6)	12.9 (6.8 to 21.5)	
Headache: Any (n = 21, 93, 114)	52.4 (29.8 to 74.3)	45.2 (34.8 to 55.8)	46.5 (37.1 to 56.1)	

Headache: Mild (n = 21, 88, 109)	47.6 (25.7 to 70.2)	38.6 (28.4 to 49.6)	40.4 (31.1 to 50.2)	
Headache: Moderate (n = 16, 82, 98)	18.8 (4 to 45.6)	28 (18.7 to 39.1)	26.5 (18.1 to 36.4)	
Headache: Severe (n = 16, 74, 90)	12.5 (1.6 to 38.3)	5.4 (1.5 to 13.3)	6.7 (2.5 to 13.9)	
Vomiting: Any (n = 16, 73, 89)	6.3 (0.2 to 30.2)	5.5 (1.5 to 13.4)	5.6 (1.8 to 12.6)	
Vomiting: Mild (n = 16, 73, 89)	6.3 (0.2 to 30.2)	5.5 (1.5 to 13.4)	5.6 (1.8 to 12.6)	
Vomiting: Moderate (n = 15, 71, 86)	0 (0 to 21.8)	0 (0 to 5.1)	0 (0 to 4.2)	
Vomiting: Severe (n = 15, 71, 86)	0 (0 to 21.8)	0 (0 to 5.1)	0 (0 to 4.2)	
Diarrhea: Any (n = 18, 83, 101)	22.2 (6.4 to 47.6)	30.1 (20.5 to 41.2)	28.7 (20.1 to 38.6)	
Diarrhea: Mild (n = 18, 82, 100)	22.2 (6.4 to 47.6)	29.3 (19.7 to 40.4)	28 (19.5 to 37.9)	
Diarrhea: Moderate (n = 15, 72, 87)	0 (0 to 21.8)	4.2 (0.9 to 11.7)	3.4 (0.7 to 9.7)	
Diarrhea: Severe (n = 15, 72, 87)	0 (0 to 21.8)	1.4 (0 to 7.5)	1.1 (0 to 6.2)	
Muscle Pain: Any (n = 24, 99, 123)	58.3 (36.6 to 77.9)	60.6 (50.3 to 70.3)	60.2 (50.9 to 68.9)	
Muscle Pain: Mild (n = 22, 92, 114)	50 (28.2 to 71.8)	50 (39.4 to 60.6)	50 (40.5 to 59.5)	
Muscle Pain: Moderate (n = 19, 80, 99)	36.8 (16.3 to 61.6)	30 (20.3 to 41.3)	31.3 (22.4 to 41.4)	
Muscle Pain: Severe (n = 16, 75, 91)	12.5 (1.6 to 38.3)	6.7 (2.2 to 14.9)	7.7 (3.1 to 15.2)	
Joint Pain: Any (n = 16, 83, 99)	25 (7.3 to 52.4)	32.5 (22.6 to 43.7)	31.3 (22.4 to 41.4)	
Joint Pain: Mild (n = 15, 78, 93)	13.3 (1.7 to 40.5)	24.4 (15.3 to 35.4)	22.6 (14.6 to 32.4)	
Joint Pain: Moderate (n = 16, 75, 91)	12.5 (1.6 to 38.3)	17.3 (9.6 to 27.8)	16.5 (9.5 to 25.7)	
Joint Pain: Severe (n = 16, 74, 90)	6.3 (0.2 to 30.2)	4.1 (0.8 to 11.4)	4.4 (1.2 to 11)	
Use of Medication to Treat Pain (n= 16, 77, 93)	18.8 (4 to 45.6)	16.9 (9.3 to 27.1)	17.2 (10.2 to 26.4)	
Use of Medication to Treat Fever (n= 17, 77, 94)	23.5 (6.8 to 49.9)	15.6 (8.3 to 25.6)	17 (10.1 to 26.2)	

Notes:

[37] - N signifies subjects with known values for any systemic event.

[38] - N signifies subjects with known values for any systemic event.

[39] - N signifies subjects with known values for any systemic event.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs/SAEs: recorded from 13vPnC Dose 1 to completion of study. Subjects recorded pre-specified AEs in electronic diary: local reactions; systemic events (up to 14 days after 13vPnC vaccination)

Adverse event reporting additional description:

AEs/SAEs were grouped by system organ class and summarized. AEs included AEs collected in electronic diary (local, systemic reactions for dose 1, 2, 3, 4 of 13vPnC; systematic assessment), on case report form at each visit (non systematic assessment). Safety population was analysed. Version was not captured, 0.0 is mentioned for dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	13vPnC Dose 3 Blood Draw to 13vPnC Dose 4

Reporting group description:

All subjects aged 2 years and above who received 4 single 0.5 mL doses of 13vPnC intramuscular injections, 13vPnC Doses 1 to 3 at 1-month intervals and 13vPnC Dose 4 at 6 months after 13vPnC Dose 3, were assessed from blood draw 1 month after 13vPnC Dose 3 to prior to administration of 13vPnC Dose 4.

Reporting group title	13vPnC Dose 1 to 13vPnC Dose 3 Blood Draw

Reporting group description:

All subjects aged 2 years and above who received 3 single 0.5 mL doses of 13vPnC intramuscular injections at 1-month intervals, were assessed from 13vPnC Dose 1 to the blood draw 1 month after 13vPnC Dose 3.

Reporting group title	13vPnC Dose 4

Reporting group description:

All subjects aged 2 years and above who received 4 single 0.5 mL doses of 13vPnC intramuscular injections, 13vPnC Doses 1 to 3 at 1-month intervals and 13vPnC Dose 4 at 6 months after 13vPnC Dose 3, were assessed from 13vPnC Dose 4 to the blood draw 1 month after 13vPnC Dose 4.

Reporting group title	23vPS Dose

Reporting group description:

All subjects aged 2 years and above who received 4 single 0.5 mL doses of 13vPnC intramuscular injections, 13vPnC Doses 1 to 3 at 1-month intervals and 13vPnC Dose 4 at 6 months after 13vPnC Dose 3, followed by single 0.5 mL dose of 23vPS intramuscular injection at 1 month after 13vPnC Dose 4, were assessed from 23vPS Dose to the blood draw 1 month after 23vPS Dose.

Reporting group title	Follow-up

Reporting group description:

All subjects aged 2 years and above who received 4 single 0.5 mL doses of 13vPnC intramuscular injections, 13vPnC Doses 1 to 3 at 1-month intervals and 13vPnC Dose 4 at 6 months after 13vPnC Dose 3, followed by single 0.5 mL dose of 23vPS intramuscular injection at 1 month after 13vPnC Dose 4, were assessed from blood draw 1 month after 23vPS Dose to 6-month follow-up.

Serious adverse events	13vPnC Dose 3 Blood Draw to 13vPnC Dose 4	13vPnC Dose 1 to 13vPnC Dose 3 Blood Draw	13vPnC Dose 4
Total subjects affected by serious adverse events			
subjects affected / exposed	42 / 221 (19.00%)	58 / 247 (23.48%)	11 / 192 (5.73%)
number of deaths (all causes)	1	11	2
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	2 / 221 (0.90%)	6 / 247 (2.43%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia recurrent			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (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
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma recurrent			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmacytoma			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Ependymoma			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Mantle cell lymphoma			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Myelodysplastic syndrome			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Refractory anaemia with an excess of blasts			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Juvenile chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Leukaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Acute myeloid leukaemia recurrent			

subjects affected / exposed	4 / 221 (1.81%)	6 / 247 (2.43%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypovolaemic shock			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypotension			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 221 (1.81%)	6 / 247 (2.43%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 4	1 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site erythema			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Death			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	1 / 221 (0.45%)	5 / 247 (2.02%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Graft versus host disease in intestine			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in liver			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in skin			
subjects affected / exposed	2 / 221 (0.90%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Uncoded	Additional description: Term was not coded because it violated sponsor's coding conventions.		
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oropharyngeal pain			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Dyspnoea			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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

Completed suicide			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Investigations			
Cytomegalovirus test positive			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
False positive investigation result			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Injury, poisoning and procedural complications			
Spinal fracture			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Sternal fracture			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (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
Cardiac failure acute			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
VIIth nerve paralysis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Headache			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (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
Blood and lymphatic system disorders			
Haemolytic anaemia			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (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
Thrombocytopenia			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia haemolytic autoimmune			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Leukopenia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Lymphadenitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Warm type haemolytic anaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial eventration			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Pancreatitis acute			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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 haemorrhage			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular injury			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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			
Renal failure			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (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
Renal failure acute			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (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
Haematuria			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (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
Nephrotic syndrome			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (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
Musculoskeletal and connective tissue			

disorders			
Musculoskeletal stiffness			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Escherichia sepsis			
subjects affected / exposed	2 / 221 (0.90%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	4 / 221 (1.81%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 221 (0.90%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (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
Appendicitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacterial sepsis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	2 / 221 (0.90%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral toxoplasmosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ear infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis viral			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingivitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Molluscum contagiosum			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Cytomegalovirus infection			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Haemophilus sepsis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Hepatic candidiasis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Hepatitis B			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Herpes virus infection			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Herpes zoster disseminated			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Meningitis			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Thrombophlebitis septic			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Varicella			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Bacterial infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Oral candidiasis			

subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (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
Hyperglycaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	23vPS Dose	Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 184 (5.98%)	28 / 247 (11.34%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia recurrent			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma recurrent			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post transplant lymphoproliferative disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ependymoma			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mantle cell lymphoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory anaemia with an excess of blasts			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Juvenile chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 184 (0.00%)	3 / 247 (1.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Hypovolaemic shock			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 184 (0.00%)	4 / 247 (1.62%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site erythema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Immune system disorders			
Graft versus host disease			
subjects affected / exposed	0 / 184 (0.00%)	2 / 247 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft versus host disease in intestine			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic graft versus host disease			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft versus host disease in liver			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft versus host disease in skin			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Uncoded	Additional description: Term was not coded because it violated sponsor's coding conventions.		

subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal pain			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Cytomegalovirus test positive			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
False positive investigation result			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Spinal fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
VIIth nerve paralysis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Haemolytic anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia haemolytic autoimmune			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	0 / 184 (0.00%)	2 / 247 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Warm type haemolytic anaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial eventration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure acute			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal stiffness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Osteonecrosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Escherichia sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 184 (0.54%)	2 / 247 (0.81%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 184 (0.00%)	4 / 247 (1.62%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral toxoplasmosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingivitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Molluscum contagiosum			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic candidiasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes virus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster disseminated			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral herpes			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonas aeruginosa			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 influenza			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis septic			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal sepsis			

subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	13vPnC Dose 3 Blood Draw to 13vPnC Dose 4	13vPnC Dose 1 to 13vPnC Dose 3 Blood Draw	13vPnC Dose 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	89 / 221 (40.27%)	203 / 247 (82.19%)	127 / 192 (66.15%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasmacytoma			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Precursor B-lymphoblastic lymphoma			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Acute leukaemia			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Kaposi's sarcoma			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Anogenital warts			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 221 (0.45%)	7 / 247 (2.83%)	0 / 192 (0.00%)
occurrences (all)	1	7	0
Hypotension			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	1	2	1
Orthostatic hypotension			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Thrombophlebitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Flushing			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hypovolaemic shock			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vasodilatation			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Venous insufficiency			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Venous thrombosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 221 (1.36%)	15 / 247 (6.07%)	3 / 192 (1.56%)
occurrences (all)	4	17	3
Pyrexia			
subjects affected / exposed	5 / 221 (2.26%)	16 / 247 (6.48%)	3 / 192 (1.56%)
occurrences (all)	5	17	3
Oedema peripheral			
subjects affected / exposed	6 / 221 (2.71%)	12 / 247 (4.86%)	0 / 192 (0.00%)
occurrences (all)	6	12	0
Asthenia			
subjects affected / exposed	2 / 221 (0.90%)	10 / 247 (4.05%)	1 / 192 (0.52%)
occurrences (all)	2	10	1
Injection site swelling			
subjects affected / exposed	0 / 221 (0.00%)	4 / 247 (1.62%)	3 / 192 (1.56%)
occurrences (all)	0	4	4
Injection site erythema			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	4 / 192 (2.08%)
occurrences (all)	0	3	5
Oedema			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Chest pain			

subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	0	2	1
Catheter site rash			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Complication of device removal			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Feeling hot			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	1	1	1
Injection site movement impairment			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	5 / 192 (2.60%)
occurrences (all)	0	1	5
Medical device complication			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Vaccination site haematoma			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Vaccination site pain			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vaccination site reaction			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Inflammation			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Vaccination site erythema			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Injection site inflammation			

subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Vaccination site oedema			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Vaccination site rash			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Fever >=38 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 221 (0.00%)	13 / 169 (7.69%)	17 / 96 (17.71%)
occurrences (all)	0	13	17
Fever >=38, <38.5 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 221 (0.00%)	10 / 167 (5.99%)	12 / 92 (13.04%)
occurrences (all)	0	10	12
Fever >=38.5, <39 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 221 (0.00%)	2 / 165 (1.21%)	5 / 90 (5.56%)
occurrences (all)	0	2	5
Fever >=39, =<40 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 221 (0.00%)	3 / 167 (1.80%)	2 / 87 (2.30%)
occurrences (all)	0	3	2
Fatigue (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 221 (0.00%)	77 / 157 (49.04%)	0 / 192 (0.00%)
occurrences (all)	0	77	0
Fatigue (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is		

	same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 221 (0.00%)	42 / 137 (30.66%)	0 / 192 (0.00%)
occurrences (all)	0	42	0
Fatigue (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 221 (0.00%)	8 / 120 (6.67%)	0 / 192 (0.00%)
occurrences (all)	0	8	0
Headache (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 221 (0.00%)	53 / 142 (37.32%)	0 / 192 (0.00%)
occurrences (all)	0	53	0
Headache (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 221 (0.00%)	44 / 138 (31.88%)	0 / 192 (0.00%)
occurrences (all)	0	44	0
Headache (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 221 (0.00%)	21 / 122 (17.21%)	0 / 192 (0.00%)
occurrences (all)	0	21	0
Headache (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 221 (0.00%)	4 / 119 (3.36%)	0 / 192 (0.00%)
occurrences (all)	0	4	0
Vomiting (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 221 (0.00%)	13 / 120 (10.83%)	0 / 192 (0.00%)
occurrences (all)	0	13	0
Vomiting (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[13]	0 / 221 (0.00%)	6 / 119 (5.04%)	0 / 192 (0.00%)
occurrences (all)	0	6	0
Vomiting (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 221 (0.00%)	8 / 117 (6.84%)	0 / 192 (0.00%)
occurrences (all)	0	8	0
Diarrhea (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 221 (0.00%)	30 / 130 (23.08%)	0 / 192 (0.00%)
occurrences (all)	0	30	0
Diarrhea (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 221 (0.00%)	26 / 128 (20.31%)	0 / 192 (0.00%)
occurrences (all)	0	26	0
Diarrhea (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 221 (0.00%)	6 / 119 (5.04%)	0 / 192 (0.00%)
occurrences (all)	0	6	0
Diarrhea (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 221 (0.00%)	2 / 117 (1.71%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Muscle pain (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 221 (0.00%)	61 / 152 (40.13%)	0 / 192 (0.00%)
occurrences (all)	0	61	0
Muscle pain (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 221 (0.00%)	47 / 142 (33.10%)	0 / 192 (0.00%)
occurrences (all)	0	47	0

Muscle pain (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 221 (0.00%)	27 / 132 (20.45%)	0 / 192 (0.00%)
occurrences (all)	0	27	0
Muscle pain (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 221 (0.00%)	4 / 118 (3.39%)	0 / 192 (0.00%)
occurrences (all)	0	4	0
Joint pain (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 221 (0.00%)	28 / 132 (21.21%)	0 / 192 (0.00%)
occurrences (all)	0	28	0
Joint pain (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 221 (0.00%)	23 / 128 (17.97%)	0 / 192 (0.00%)
occurrences (all)	0	23	0
Joint pain (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 221 (0.00%)	13 / 122 (10.66%)	0 / 192 (0.00%)
occurrences (all)	0	13	0
Joint pain (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 221 (0.00%)	4 / 119 (3.36%)	0 / 192 (0.00%)
occurrences (all)	0	4	0
Fever >=38 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 221 (0.00%)	13 / 131 (9.92%)	0 / 192 (0.00%)
occurrences (all)	0	13	0
Fever >=38, <38.5 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 221 (0.00%)	11 / 131 (8.40%)	0 / 192 (0.00%)
occurrences (all)	0	11	0
Fever >=38.5, <39 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 221 (0.00%)	3 / 126 (2.38%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Fever >=39, =<40 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 221 (0.00%)	3 / 126 (2.38%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Fever >=38 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 221 (0.00%)	8 / 120 (6.67%)	0 / 192 (0.00%)
occurrences (all)	0	8	0
Fever >=38, <38.5 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 221 (0.00%)	6 / 119 (5.04%)	0 / 192 (0.00%)
occurrences (all)	0	6	0
Fever >=38.5, <39 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 221 (0.00%)	4 / 117 (3.42%)	0 / 192 (0.00%)
occurrences (all)	0	4	0
Fever >=39, =<40 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 221 (0.00%)	2 / 116 (1.72%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Fatigue (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[35]	0 / 221 (0.00%)	119 / 204 (58.33%)	86 / 128 (67.19%)
occurrences (all)	0	119	86
Fatigue (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 221 (0.00%)	88 / 190 (46.32%)	68 / 121 (56.20%)
occurrences (all)	0	88	68
Fatigue (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 221 (0.00%)	69 / 192 (35.94%)	48 / 106 (45.28%)
occurrences (all)	0	69	48
Fatigue (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 221 (0.00%)	20 / 173 (11.56%)	12 / 93 (12.90%)
occurrences (all)	0	20	12
Fatigue (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 221 (0.00%)	91 / 171 (53.22%)	0 / 192 (0.00%)
occurrences (all)	0	91	0
Fatigue (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[40]	0 / 221 (0.00%)	63 / 156 (40.38%)	0 / 192 (0.00%)
occurrences (all)	0	63	0
Fatigue (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 221 (0.00%)	61 / 155 (39.35%)	0 / 192 (0.00%)
occurrences (all)	0	61	0
Fatigue (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 221 (0.00%)	13 / 131 (9.92%)	0 / 192 (0.00%)
occurrences (all)	0	13	0

Headache (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 221 (0.00%)	84 / 189 (44.44%)	53 / 114 (46.49%)
occurrences (all)	0	84	53
Headache (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 221 (0.00%)	71 / 186 (38.17%)	44 / 109 (40.37%)
occurrences (all)	0	71	44
Headache (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 221 (0.00%)	31 / 174 (17.82%)	26 / 98 (26.53%)
occurrences (all)	0	31	26
Headache (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 221 (0.00%)	6 / 167 (3.59%)	6 / 90 (6.67%)
occurrences (all)	0	4	6
Headache (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[47]	0 / 221 (0.00%)	53 / 152 (34.87%)	0 / 192 (0.00%)
occurrences (all)	0	53	0
Headache (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[48]	0 / 221 (0.00%)	44 / 147 (29.93%)	0 / 192 (0.00%)
occurrences (all)	0	44	0
Headache (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[49]	0 / 221 (0.00%)	20 / 136 (14.71%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Headache (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative assessment type: Systematic			
subjects affected / exposed[50]	0 / 221 (0.00%)	2 / 128 (1.56%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Vomiting (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[51]	0 / 221 (0.00%)	36 / 173 (20.81%)	5 / 89 (5.62%)
occurrences (all)	0	36	5
Vomiting (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[52]	0 / 221 (0.00%)	31 / 172 (18.02%)	5 / 89 (5.62%)
occurrences (all)	0	31	5
Vomiting (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[53]	0 / 221 (0.00%)	6 / 166 (3.61%)	0 / 86 (0.00%)
occurrences (all)	0	6	0
Vomiting (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[54]	0 / 221 (0.00%)	2 / 165 (1.21%)	0 / 86 (0.00%)
occurrences (all)	0	2	0
Vomiting (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[55]	0 / 221 (0.00%)	20 / 135 (14.81%)	0 / 192 (0.00%)
occurrences (all)	0	20	0
Vomiting (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[56]	0 / 221 (0.00%)	16 / 134 (11.94%)	0 / 192 (0.00%)
occurrences (all)	0	16	0
Vomiting (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[57]	0 / 221 (0.00%)	9 / 131 (6.87%)	0 / 192 (0.00%)
occurrences (all)	0	9	0
Vomiting (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[58]	0 / 221 (0.00%)	1 / 126 (0.79%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Diarrhea (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[59]	0 / 221 (0.00%)	66 / 189 (34.92%)	29 / 101 (28.71%)
occurrences (all)	0	66	29
Diarrhea (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[60]	0 / 221 (0.00%)	62 / 186 (33.33%)	28 / 100 (28.00%)
occurrences (all)	0	62	28
Diarrhea (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[61]	0 / 221 (0.00%)	14 / 171 (8.19%)	3 / 87 (3.45%)
occurrences (all)	0	14	3
Diarrhea (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[62]	0 / 221 (0.00%)	5 / 168 (2.98%)	1 / 87 (1.15%)
occurrences (all)	0	5	1
Diarrhea (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[63]	0 / 221 (0.00%)	44 / 150 (29.33%)	0 / 192 (0.00%)
occurrences (all)	0	44	0
Diarrhea (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[64]	0 / 221 (0.00%)	41 / 149 (27.52%)	0 / 192 (0.00%)
occurrences (all)	0	41	0

Diarrhea (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[65]	0 / 221 (0.00%)	13 / 134 (9.70%)	0 / 192 (0.00%)
occurrences (all)	0	13	0
Diarrhea (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[66]	0 / 221 (0.00%)	2 / 127 (1.57%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Muscle pain (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[67]	0 / 221 (0.00%)	103 / 201 (51.24%)	74 / 123 (60.16%)
occurrences (all)	0	103	74
Muscle pain (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[68]	0 / 221 (0.00%)	83 / 191 (43.46%)	57 / 114 (50.00%)
occurrences (all)	0	83	57
Muscle pain (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[69]	0 / 221 (0.00%)	46 / 183 (25.14%)	31 / 99 (31.31%)
occurrences (all)	0	46	31
Muscle pain (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[70]	0 / 221 (0.00%)	9 / 168 (5.36%)	7 / 91 (7.69%)
occurrences (all)	0	9	7
Muscle pain (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[71]	0 / 221 (0.00%)	72 / 160 (45.00%)	0 / 192 (0.00%)
occurrences (all)	0	72	0
Muscle pain (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type:			

Systematic			
subjects affected / exposed[72]	0 / 221 (0.00%)	54 / 150 (36.00%)	0 / 192 (0.00%)
occurrences (all)	0	54	0
Muscle pain (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[73]	0 / 221 (0.00%)	40 / 143 (27.97%)	0 / 192 (0.00%)
occurrences (all)	0	40	0
Muscle pain (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[74]	0 / 221 (0.00%)	8 / 131 (6.11%)	0 / 192 (0.00%)
occurrences (all)	0	8	0
Joint pain (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[75]	0 / 221 (0.00%)	34 / 176 (19.32%)	21 / 93 (22.58%)
occurrences (all)	0	34	21
Joint pain (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[76]	0 / 221 (0.00%)	34 / 176 (19.32%)	21 / 93 (22.58%)
occurrences (all)	0	34	21
Joint pain (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[77]	0 / 221 (0.00%)	24 / 175 (13.71%)	15 / 91 (16.48%)
occurrences (all)	0	24	15
Joint pain (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[78]	0 / 221 (0.00%)	5 / 167 (2.99%)	4 / 90 (4.44%)
occurrences (all)	0	5	4
Joint pain (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[79]	0 / 221 (0.00%)	37 / 147 (25.17%)	0 / 192 (0.00%)
occurrences (all)	0	37	0
Joint pain (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[80]	0 / 221 (0.00%)	30 / 142 (21.13%)	0 / 192 (0.00%)
occurrences (all)	0	30	0
Joint pain (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[81]	0 / 221 (0.00%)	20 / 136 (14.71%)	0 / 192 (0.00%)
occurrences (all)	0	20	0
Joint pain (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[82]	0 / 221 (0.00%)	3 / 129 (2.33%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	8 / 221 (3.62%)	21 / 247 (8.50%)	2 / 192 (1.04%)
occurrences (all)	9	24	2
Chronic graft versus host disease			
subjects affected / exposed	3 / 221 (1.36%)	12 / 247 (4.86%)	0 / 192 (0.00%)
occurrences (all)	3	14	0
Graft versus host disease in liver			
subjects affected / exposed	1 / 221 (0.45%)	5 / 247 (2.02%)	0 / 192 (0.00%)
occurrences (all)	1	7	0
Graft versus host disease in skin			
subjects affected / exposed	6 / 221 (2.71%)	4 / 247 (1.62%)	0 / 192 (0.00%)
occurrences (all)	7	4	0
Food allergy			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	0	3	1
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Acute graft versus host disease			

subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Chronic graft versus host disease in liver			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Graft versus host disease in intestine			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Gynaecomastia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal dryness			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Prostatitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Genital discharge			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Amenorrhoea			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	2 / 221 (0.90%)	24 / 247 (9.72%)	4 / 192 (2.08%)
occurrences (all)	2	24	4
Dyspnoea exertional			
subjects affected / exposed	1 / 221 (0.45%)	4 / 247 (1.62%)	1 / 192 (0.52%)
occurrences (all)	1	4	1
Rhinorrhoea			
subjects affected / exposed	1 / 221 (0.45%)	4 / 247 (1.62%)	2 / 192 (1.04%)
occurrences (all)	1	4	2
Lung disorder			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Lung infiltration			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal plaque			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Pulmonary mass			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Hyperventilation			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Organising pneumonia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0

Oropharyngeal pain			
subjects affected / exposed	1 / 221 (0.45%)	8 / 247 (3.24%)	0 / 192 (0.00%)
occurrences (all)	1	8	0
Pneumonitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Sputum discoloured			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 221 (0.45%)	5 / 247 (2.02%)	0 / 192 (0.00%)
occurrences (all)	1	6	0
Insomnia			
subjects affected / exposed	1 / 221 (0.45%)	4 / 247 (1.62%)	1 / 192 (0.52%)
occurrences (all)	1	5	1
Sleep disorder			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	0	2	1
Confusional state			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Nervousness			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood testosterone decreased			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Liver function test abnormal			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	0	2	1
Neutrophil count decreased			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	1	2	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Human herpes virus 6 serology positive			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Intraocular pressure increased			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Thyroxine decreased			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Serum ferritin increased			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	2	0	1
Cystogram			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Ejection fraction abnormal			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Transfusion reaction			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Laceration			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Ligament sprain			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Eye injury			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Febrile nonhaemolytic transfusion reaction			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Conjunctival scar			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Drug administration error			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Post-traumatic pain			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Procedural pain			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Anaemia postoperative			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Myotonic dystrophy			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Ichthyosis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Arrhythmia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Atrial thrombosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Dilatation ventricular			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Myocardial infarction			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Cardiomyopathy			

subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Polyneuropathy			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Post herpetic neuralgia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Sinus headache			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Amnesia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Migraine with aura			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Cranial nerve palsies multiple			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0

Epilepsy			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Headache			
subjects affected / exposed	3 / 221 (1.36%)	13 / 247 (5.26%)	4 / 192 (2.08%)
occurrences (all)	3	13	5
Balance disorder			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Paraesthesia			
subjects affected / exposed	2 / 221 (0.90%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	2	2	0
Coordination abnormal			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Myoclonus			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Nervous system disorder			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	2 / 221 (0.90%)	5 / 247 (2.02%)	0 / 192 (0.00%)
occurrences (all)	2	6	0
Eosinophilia			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Anaemia			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Aplasia pure red cell			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Anaemia macrocytic			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Aplastic anaemia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Febrile neutropenia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Histiocytosis haematophagic			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Normochromic normocytic anaemia			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Pancytopenia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Splenomegaly			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Haemolytic uraemic syndrome			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	2 / 221 (0.90%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	2	3	0
Vertigo			
subjects affected / exposed	1 / 221 (0.45%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	1	3	0
Tinnitus			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Ear discomfort			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hearing impaired			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Middle ear effusion			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane disorder			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Deafness neurosensory			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Deafness unilateral			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Cerumen impaction			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 221 (0.00%)	6 / 247 (2.43%)	0 / 192 (0.00%)
occurrences (all)	0	7	0
Dry eye			
subjects affected / exposed	3 / 221 (1.36%)	5 / 247 (2.02%)	1 / 192 (0.52%)
occurrences (all)	3	5	1
Allergic keratitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Diabetic retinopathy			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Eye haemorrhage			

subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Retinal detachment			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Xerophthalmia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 221 (0.90%)	24 / 247 (9.72%)	3 / 192 (1.56%)
occurrences (all)	2	27	3
Vomiting			
subjects affected / exposed	1 / 221 (0.45%)	15 / 247 (6.07%)	0 / 192 (0.00%)
occurrences (all)	1	21	0
Nausea			
subjects affected / exposed	0 / 221 (0.00%)	8 / 247 (3.24%)	0 / 192 (0.00%)
occurrences (all)	0	10	0
Abdominal pain			
subjects affected / exposed	1 / 221 (0.45%)	8 / 247 (3.24%)	2 / 192 (1.04%)
occurrences (all)	1	9	2
Abdominal pain upper			
subjects affected / exposed	1 / 221 (0.45%)	5 / 247 (2.02%)	0 / 192 (0.00%)
occurrences (all)	1	5	0
Stomatitis			
subjects affected / exposed	2 / 221 (0.90%)	5 / 247 (2.02%)	1 / 192 (0.52%)
occurrences (all)	2	5	1
Constipation			
subjects affected / exposed	2 / 221 (0.90%)	4 / 247 (1.62%)	1 / 192 (0.52%)
occurrences (all)	2	4	1
Dry mouth			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0

Dysphagia			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Aphthous stomatitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Dyspepsia			
subjects affected / exposed	3 / 221 (1.36%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	3	2	1
Gastrointestinal pain			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	0	2	1
Oesophagitis			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Abdominal pain lower			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Aptyalism			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Eructation			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Faecaloma			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Glossodynia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hyperchlorhydria			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Lip swelling			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Oral disorder			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Oral mucosal discolouration			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Tongue coated			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Oral lichen planus			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Odynophagia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0

subjects affected / exposed	0 / 221 (0.00%)	4 / 247 (1.62%)	0 / 192 (0.00%)
occurrences (all)	0	4	0
Erythema			
subjects affected / exposed	1 / 221 (0.45%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	1	3	0
Skin lesion			
subjects affected / exposed	1 / 221 (0.45%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	1	3	0
Acne			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Rash macular			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Rash papular			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Blister			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Dermatosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Generalised erythema			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Lichenification			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	1	1	1
Perivascular dermatitis			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Rash generalised			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Skin discolouration			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Skin mass			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Pityriasis rubra pilaris			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Dermatitis atopic			

subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Redness (Any) : 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[83]	0 / 221 (0.00%)	23 / 168 (13.69%)	33 / 100 (33.00%)
occurrences (all)	0	23	33
Redness (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[84]	0 / 221 (0.00%)	20 / 168 (11.90%)	22 / 97 (22.68%)
occurrences (all)	0	20	22
Redness (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[85]	0 / 221 (0.00%)	6 / 165 (3.64%)	16 / 90 (17.78%)
occurrences (all)	0	6	16
Redness (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[86]	0 / 221 (0.00%)	0 / 247 (0.00%)	5 / 89 (5.62%)
occurrences (all)	0	0	5
Swelling (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[87]	0 / 221 (0.00%)	25 / 170 (14.71%)	41 / 108 (37.96%)
occurrences (all)	0	25	41
Swelling (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[88]	0 / 221 (0.00%)	18 / 169 (10.65%)	25 / 100 (25.00%)
occurrences (all)	0	18	25
Swelling (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[89]	0 / 221 (0.00%)	9 / 167 (5.39%)	17 / 95 (17.89%)
occurrences (all)	0	9	17
Swelling (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[90]	0 / 221 (0.00%)	1 / 165 (0.61%)	4 / 88 (4.55%)
occurrences (all)	0	1	4
Pain (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[91]	0 / 221 (0.00%)	165 / 222 (74.32%)	113 / 143 (79.02%)
occurrences (all)	0	165	113
Pain (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[92]	0 / 221 (0.00%)	151 / 217 (69.59%)	94 / 130 (72.31%)
occurrences (all)	0	151	94
Pain (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[93]	0 / 221 (0.00%)	50 / 180 (27.78%)	42 / 109 (38.53%)
occurrences (all)	0	50	42

Pain (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[94]	0 / 221 (0.00%)	5 / 166 (3.01%)	6 / 90 (6.67%)
occurrences (all)	0	5	6
Redness (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[95]	0 / 221 (0.00%)	30 / 137 (21.90%)	0 / 192 (0.00%)
occurrences (all)	0	30	0
Redness (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[96]	0 / 221 (0.00%)	26 / 134 (19.40%)	0 / 192 (0.00%)
occurrences (all)	0	26	0
Redness (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[97]	0 / 221 (0.00%)	9 / 129 (6.98%)	0 / 192 (0.00%)
occurrences (all)	0	9	0
Redness (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[98]	0 / 221 (0.00%)	2 / 127 (1.57%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Swelling (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[99]	0 / 221 (0.00%)	25 / 133 (18.80%)	0 / 192 (0.00%)
occurrences (all)	0	25	0
Swelling (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[100]	0 / 221 (0.00%)	19 / 131 (14.50%)	0 / 192 (0.00%)
occurrences (all)	0	19	0
Swelling (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type:			

Systematic			
subjects affected / exposed[101]	0 / 221 (0.00%)	7 / 128 (5.47%)	0 / 192 (0.00%)
occurrences (all)	0	7	0
Pain (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[102]	0 / 221 (0.00%)	146 / 194 (75.26%)	0 / 192 (0.00%)
occurrences (all)	0	146	0
Pain (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[103]	0 / 221 (0.00%)	129 / 184 (70.11%)	0 / 192 (0.00%)
occurrences (all)	0	129	0
Pain (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[104]	0 / 221 (0.00%)	49 / 148 (33.11%)	0 / 192 (0.00%)
occurrences (all)	0	49	0
Pain (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[105]	0 / 221 (0.00%)	6 / 131 (4.58%)	0 / 192 (0.00%)
occurrences (all)	0	6	0
Redness (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[106]	0 / 221 (0.00%)	17 / 120 (14.17%)	0 / 192 (0.00%)
occurrences (all)	0	17	0
Redness (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[107]	0 / 221 (0.00%)	13 / 118 (11.02%)	0 / 192 (0.00%)
occurrences (all)	0	13	0
Redness (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[108]	0 / 221 (0.00%)	6 / 117 (5.13%)	0 / 192 (0.00%)

Pain (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[116]	0 / 221 (0.00%)	42 / 141 (29.79%)	0 / 192 (0.00%)
occurrences (all)	0	42	0
Pain (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[117]	0 / 221 (0.00%)	5 / 117 (4.27%)	0 / 192 (0.00%)
occurrences (all)	0	5	0
Fatigue (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[118]	0 / 221 (0.00%)	58 / 148 (39.19%)	0 / 192 (0.00%)
occurrences (all)	0	58	0
Renal and urinary disorders			
Polyuria			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	4	0
Renal failure			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Dysuria			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Nocturia			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Pollakiuria			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Haematuria			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Incontinence			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Renal impairment			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Urethral pain			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Urinary tract disorder			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Urine abnormality			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hyperthyroidism			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Cushing's syndrome			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	1	0	1
Oestrogen deficiency			

subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 221 (2.71%)	11 / 247 (4.45%)	4 / 192 (2.08%)
occurrences (all)	7	11	6
Muscle spasms			
subjects affected / exposed	2 / 221 (0.90%)	7 / 247 (2.83%)	2 / 192 (1.04%)
occurrences (all)	2	9	2
Back pain			
subjects affected / exposed	1 / 221 (0.45%)	7 / 247 (2.83%)	0 / 192 (0.00%)
occurrences (all)	1	8	0
Myalgia			
subjects affected / exposed	1 / 221 (0.45%)	5 / 247 (2.02%)	1 / 192 (0.52%)
occurrences (all)	1	5	1
Musculoskeletal pain			
subjects affected / exposed	2 / 221 (0.90%)	4 / 247 (1.62%)	0 / 192 (0.00%)
occurrences (all)	2	4	0
Pain in extremity			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	1 / 192 (0.52%)
occurrences (all)	0	3	1
Musculoskeletal stiffness			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Bone pain			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Joint stiffness			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Myopathy			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Osteonecrosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Osteoporosis			
subjects affected / exposed	3 / 221 (1.36%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	3	1	0
Synovial cyst			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Osteopenia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Spinal osteoarthritis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Sjogren's syndrome			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 221 (2.71%)	28 / 247 (11.34%)	11 / 192 (5.73%)
occurrences (all)	6	32	11

Cytomegalovirus infection			
subjects affected / exposed	3 / 221 (1.36%)	10 / 247 (4.05%)	1 / 192 (0.52%)
occurrences (all)	4	12	1
Upper respiratory tract infection			
subjects affected / exposed	6 / 221 (2.71%)	10 / 247 (4.05%)	3 / 192 (1.56%)
occurrences (all)	8	12	3
Herpes zoster			
subjects affected / exposed	5 / 221 (2.26%)	8 / 247 (3.24%)	0 / 192 (0.00%)
occurrences (all)	5	11	0
Bronchitis			
subjects affected / exposed	3 / 221 (1.36%)	6 / 247 (2.43%)	1 / 192 (0.52%)
occurrences (all)	3	6	1
Sinusitis			
subjects affected / exposed	1 / 221 (0.45%)	5 / 247 (2.02%)	0 / 192 (0.00%)
occurrences (all)	1	6	0
Tonsillitis			
subjects affected / exposed	0 / 221 (0.00%)	5 / 247 (2.02%)	1 / 192 (0.52%)
occurrences (all)	0	5	1
Urinary tract infection			
subjects affected / exposed	2 / 221 (0.90%)	4 / 247 (1.62%)	0 / 192 (0.00%)
occurrences (all)	2	5	0
Oral fungal infection			
subjects affected / exposed	1 / 221 (0.45%)	4 / 247 (1.62%)	0 / 192 (0.00%)
occurrences (all)	1	4	0
Rhinitis			
subjects affected / exposed	3 / 221 (1.36%)	4 / 247 (1.62%)	0 / 192 (0.00%)
occurrences (all)	3	4	0
Escherichia infection			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Oral candidiasis			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	3	0

Oral herpes			
subjects affected / exposed	4 / 221 (1.81%)	3 / 247 (1.21%)	1 / 192 (0.52%)
occurrences (all)	4	3	1
Candidiasis			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Enterobacter sepsis			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Escherichia sepsis			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Eye infection			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Otitis media			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Pharyngitis			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	1 / 192 (0.52%)
occurrences (all)	0	2	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Viral infection			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Adenovirus infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Aspergillosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Bacterial infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Catheter site infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis viral			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Enterobacter infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Enterococcal sepsis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Febrile infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Gastroenteritis viral			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Genital infection fungal			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0

Herpes simplex			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	3 / 221 (1.36%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	3	1	0
Laryngitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Mycoplasma infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Pseudomonas infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Respiratory moniliasis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Staphylococcal sepsis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Systemic candida			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Acute sinusitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0

Bronchitis viral			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Hepatitis B			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Herpes zoster oticus			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Oesophageal candidiasis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Periorbital cellulitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Streptococcal urinary tract infection			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Viral pharyngitis			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0

Chronic sinusitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	2 / 192 (1.04%)
occurrences (all)	0	0	2
Herpes virus infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Infected dermal cyst			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Pharyngotonsillitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Toxoplasmosis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Viral rhinitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
		0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 221 (0.45%)	7 / 247 (2.83%)	0 / 192 (0.00%)
occurrences (all)	1	8	0
Fluid retention			
subjects affected / exposed	0 / 221 (0.00%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	0	3	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 221 (0.45%)	3 / 247 (1.21%)	0 / 192 (0.00%)
occurrences (all)	1	3	0
Diabetes mellitus			
subjects affected / exposed	1 / 221 (0.45%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	1	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia			
subjects affected / exposed	0 / 221 (0.00%)	2 / 247 (0.81%)	0 / 192 (0.00%)
occurrences (all)	0	2	0
Cachexia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Folate deficiency			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hypercreatininaemia			
subjects affected / exposed	1 / 221 (0.45%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	1	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	1 / 192 (0.52%)
occurrences (all)	0	1	1
Hypophosphataemia			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vitamin K deficiency			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Glucose tolerance impaired			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Haemochromatosis			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	23vPS Dose	Follow-up	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	93 / 184 (50.54%)	19 / 247 (7.69%)	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasmacytoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Precursor B-lymphoblastic lymphoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Acute leukaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Kaposi's sarcoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Anogenital warts			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Orthostatic hypotension			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Thrombophlebitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypovolaemic shock			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vasodilatation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Venous insufficiency			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Venous thrombosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Haematoma			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Vena cava thrombosis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 184 (2.72%)	0 / 247 (0.00%)	
occurrences (all)	6	0	
Pyrexia			
subjects affected / exposed	8 / 184 (4.35%)	1 / 247 (0.40%)	
occurrences (all)	8	2	
Oedema peripheral			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Asthenia			
subjects affected / exposed	3 / 184 (1.63%)	1 / 247 (0.40%)	
occurrences (all)	3	1	
Injection site swelling			

subjects affected / exposed	8 / 184 (4.35%)	0 / 247 (0.00%)	
occurrences (all)	9	0	
Injection site erythema			
subjects affected / exposed	5 / 184 (2.72%)	0 / 247 (0.00%)	
occurrences (all)	5	0	
Oedema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Catheter site rash			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Chest discomfort			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Complication of device removal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Feeling cold			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Feeling hot			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Injection site movement impairment			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Injection site pain			

subjects affected / exposed	8 / 184 (4.35%)	0 / 247 (0.00%)	
occurrences (all)	8	0	
Medical device complication			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vaccination site haematoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vaccination site pain			
subjects affected / exposed	6 / 184 (3.26%)	0 / 247 (0.00%)	
occurrences (all)	6	0	
Vaccination site reaction			
subjects affected / exposed	4 / 184 (2.17%)	0 / 247 (0.00%)	
occurrences (all)	4	0	
Inflammation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Spinal pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Injection site pruritus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Mucosal inflammation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vaccination site erythema			

subjects affected / exposed	5 / 184 (2.72%)	0 / 247 (0.00%)	
occurrences (all)	5	0	
Vaccination site swelling			
subjects affected / exposed	4 / 184 (2.17%)	0 / 247 (0.00%)	
occurrences (all)	4	0	
Injection site induration			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Injection site inflammation			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Vaccination site oedema			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Vaccination site rash			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Hernia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Fever >=38 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38, <38.5 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38.5, <39 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=39, =<40 degrees C: 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		

alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[11]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[15]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Muscle pain (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[21]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type:			

Systematic			
subjects affected / exposed[26]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[27]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38, <38.5 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38.5, <39 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=39, =<40 degrees C: 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38, <38.5 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=38.5, <39 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[33]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fever >=39, =<40 degrees C: 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[36]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[37]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[38]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[39]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[40]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[41]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[42]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[43]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[44]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[45]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[46]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[47]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[48]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[49]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[50]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[51]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[52]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[53]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[54]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Vomiting (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[55]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[56]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[57]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vomiting (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[58]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[59]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[60]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[61]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type:			

Systematic			
subjects affected / exposed[62]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[63]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[64]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[65]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diarrhea (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[66]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[67]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[68]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[69]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[70]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[71]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[72]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[73]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscle pain (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[74]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[75]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[76]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Joint pain (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[77]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[78]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[79]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[80]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[81]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint pain (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e--diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[82]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	4 / 184 (2.17%)	0 / 247 (0.00%)	
occurrences (all)	4	0	
Chronic graft versus host disease			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)	3	0	

Graft versus host disease in liver			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Graft versus host disease in skin			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Food allergy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Acute graft versus host disease			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Chronic graft versus host disease in liver			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Graft versus host disease in intestine			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypersensitivity			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Gynaecomastia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal discomfort			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal dryness			

subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Prostatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Genital discharge			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Amenorrhoea			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 184 (3.80%)	2 / 247 (0.81%)	
occurrences (all)	7	2	
Dyspnoea exertional			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)	3	0	
Lung disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Lung infiltration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal plaque			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pulmonary mass			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Hyperventilation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Organising pneumonia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pneumonitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Rhonchi			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Sputum discoloured			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Epistaxis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	2	
Pleural effusion			
subjects affected / exposed	0 / 184 (0.00%)	2 / 247 (0.81%)	
occurrences (all)	0	2	
Laryngeal oedema			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Sleep disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Confusional state			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Nervousness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Stress			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Investigations			
Blood testosterone decreased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Liver function test abnormal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)	3	0	
Alanine aminotransferase increased			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Blood potassium decreased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Human herpes virus 6 serology positive			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Intraocular pressure increased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Thyroxine decreased			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Serum ferritin increased			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cystogram			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ejection fraction abnormal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hepatic enzyme increased			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Blood creatinine increased			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Body temperature increased			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Transaminases increased			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Transfusion reaction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Laceration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Eye injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Conjunctival scar			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Drug administration error			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Post-traumatic pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Rib fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Arthropod bite			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Anaemia postoperative			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Congenital, familial and genetic disorders			
Myotonic dystrophy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ichthyosis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Arrhythmia			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Atrial thrombosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dilatation ventricular			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Myocardial infarction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cardiomyopathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Polyneuropathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Post herpetic neuralgia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Sciatica			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Sinus headache			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Amnesia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Migraine with aura			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Disturbance in attention			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cranial nerve palsies multiple			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Epilepsy			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Hypoaesthesia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Restless legs syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)	3	0	
Balance disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Paraesthesia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Coordination abnormal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperaesthesia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Myoclonus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Nervous system disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Eosinophilia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Aplasia pure red cell			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Anaemia macrocytic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Aplastic anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Febrile neutropenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Histiocytosis haematophagic			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pancytopenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Splenomegaly			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Vertigo			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Tinnitus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ear discomfort			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hearing impaired			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypoacusis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Middle ear effusion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Tympanic membrane disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Deafness neurosensory			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Deafness unilateral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cerumen impaction			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Ear pruritus			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Dry eye			

subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Allergic keratitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Conjunctival hyperaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Diabetic retinopathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Eye haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Eye irritation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Foreign body sensation in eyes			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Keratitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Orbital oedema			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Vision blurred			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Visual acuity reduced			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Vitreous detachment			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Blindness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cataract			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Periorbital oedema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Eye inflammation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Retinal detachment			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Xerophthalmia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Lacrimation increased			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 184 (1.63%)	1 / 247 (0.40%)	
occurrences (all)	3	1	
Vomiting			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	1 / 184 (0.54%)	2 / 247 (0.81%)	
occurrences (all)	1	2	
Abdominal pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Abdominal pain upper			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Dry mouth			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dysphagia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Aphthous stomatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oesophagitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Aptyalism			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Eructation			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Faecaloma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Glossodynia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperchlorhydria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Lip swelling			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oral disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oral mucosal discolouration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oral pain			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Tongue coated			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Tongue discolouration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oral lichen planus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Odynophagia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Sensitivity of teeth			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorder			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Inguinal hernia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hepatocellular injury			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Hepatomegaly			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cholestasis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Pruritus			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Erythema			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Skin lesion			
subjects affected / exposed			

Dermatosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Generalised erythema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Lichenification			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Perivascular dermatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Rash generalised			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Skin discolouration			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Skin hyperpigmentation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Skin mass			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Hyperhidrosis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Pityriasis rubra pilaris			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Angioedema			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Intertrigo			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Pruritus generalised			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Alopecia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Redness (Any) : 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[83]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one		

	occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[84]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[85]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[86]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[87]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[88]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[89]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[90]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Any): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[91]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Mild): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[92]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Moderate): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[93]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Severe): 13vPnC Dose 1 and Dose 4	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[94]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[95]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[96]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[97]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[98]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Swelling (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[99]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[100]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[101]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Any): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[102]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Mild): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[103]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Moderate): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[104]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Severe): 13vPnC Dose 2	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[105]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type:			

Systematic			
subjects affected / exposed[106]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[107]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[108]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Redness (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[109]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[110]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[111]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[112]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Swelling (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			

subjects affected / exposed[113]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Any): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[114]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[115]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Moderate): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[116]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain (Severe): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[117]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fatigue (Mild): 13vPnC Dose 3	Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.		
alternative assessment type: Systematic			
subjects affected / exposed[118]	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Polyuria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Renal failure			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Nocturia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Incontinence			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Renal impairment			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Urethral pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Urinary retention			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Urinary tract disorder			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Urine abnormality			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Cushingoid			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperthyroidism			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cushing's syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oestrogen deficiency			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 184 (1.63%)	2 / 247 (0.81%)	
occurrences (all)	3	2	
Muscle spasms			
subjects affected / exposed	1 / 184 (0.54%)	1 / 247 (0.40%)	
occurrences (all)	1	1	
Back pain			
subjects affected / exposed	2 / 184 (1.09%)	1 / 247 (0.40%)	
occurrences (all)	2	1	
Myalgia			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)	3	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal stiffness			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Joint stiffness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Myopathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Osteonecrosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Osteoporosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Synovial cyst			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Osteopenia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Tendonitis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Sjogren's syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Osteoarthritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	9 / 184 (4.89%)	0 / 247 (0.00%)	
occurrences (all)	9	0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	3 / 184 (1.63%)	1 / 247 (0.40%)	
occurrences (all)	3	1	
Herpes zoster			
subjects affected / exposed	1 / 184 (0.54%)	2 / 247 (0.81%)	
occurrences (all)	1	2	
Bronchitis			
subjects affected / exposed	2 / 184 (1.09%)	1 / 247 (0.40%)	
occurrences (all)	2	1	
Sinusitis			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Tonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Oral fungal infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Rhinitis			
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)	
occurrences (all)	2	0	
Escherichia infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Oral candidiasis			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)		0	

Respiratory tract infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Adenovirus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Aspergillosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Bacterial infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Catheter site infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Enterobacter infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Enterococcal sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Epstein-Barr virus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Febrile infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Folliculitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fungal infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	10	0	
Genital infection fungal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Laryngitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Mycoplasma infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pseudomonas infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Respiratory moniliasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Systemic candida			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Acute sinusitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Bronchitis viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hepatitis B			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Herpes zoster oticus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Oesophageal candidiasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Periorbital cellulitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	

Sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Staphylococcal infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Streptococcal urinary tract infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Viral pharyngitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Chronic sinusitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Herpes virus infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Infected dermal cyst			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Lung infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Pharyngotonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Toxoplasmosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Viral rhinitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	

Gastrointestinal infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Injection site cellulitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Trichosporon infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)	
occurrences (all)	0	1	
Rash pustular			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 184 (0.54%)	1 / 247 (0.40%)	
occurrences (all)	1	1	
Fluid retention			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypercholesterolaemia			
subjects affected / exposed	3 / 184 (1.63%)	0 / 247 (0.00%)	
occurrences (all)	3	0	
Diabetes mellitus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Cachexia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Dehydration			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Folate deficiency			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypercreatininaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperphosphataemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Metabolic acidosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vitamin D deficiency			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Vitamin K deficiency			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Glucose tolerance impaired			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Haemochromatosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			

subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)	
occurrences (all)	0	0	
Hyperlipidaemia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)	
occurrences (all)	1	0	

Notes:

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[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
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Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.
[103] - 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.
[104] - 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.
[105] - 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.
[106] - 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.
[107] - 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.
[108] - 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.
[109] - 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.
[110] - 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.
[111] - 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.
[112] - 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.

[113] - 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.
[114] - 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.
[115] - 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.
[116] - 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.
[117] - 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.
[118] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification:
Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 November 2009	An exclusion criteria of receipt of advanced therapy medicinal products (ATMP) including gene therapy products, somatic cell therapy products and tissue engineered products at any time before enrollment was added. Clarification regarding administration of unassigned investigational product, relapse of underlying disease and receipt of chemotherapy were added.
14 February 2012	An SAE was to be reported to Pfizer within 24 hours of investigator awareness and SAEs occurring to a subject after the study was over were to be reported to the sponsor if the investigator becomes aware of them were added. Addition of the definition of an AE (requiring documentation on CRF) was extended to include medication error and uses outside what was foreseen in the protocol, including overdose, misuse and dependency of the product, it also included drug withdrawal, extravasation, drug interactions, exposure during pregnancy, and exposure via breastfeeding. Addition of pregnancy of subject or partner required completion of the exposure in utero form (EIU) (and EIU Pregnant Partner Release of Information Form as appropriate) and additionally, if the outcome was not a live healthy birth, an SAE form was completed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported