



## 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)
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##### 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:

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**Subjects enrolled per age group**

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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

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## 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
<b>Arm title</b>	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

<b>Arm title</b>	13vPnC, 23vPS (Adult Subjects)
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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.

<b>Number of subjects in period 1</b>	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)
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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)
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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

## End points

### End points 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.	
Subject analysis set title	13vPnC, 23vPS (All Subjects)
Subject analysis set type	Full analysis
Subject analysis set description: All subjects aged 2 years and above received 4 single 0.5 mL doses of 13vPnC intramuscular injections followed by single 0.5 mL dose of 23vPS intramuscular injection. 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.	

### Primary: 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 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 3 in All Subjects <sup>[1]</sup>
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. Confidence interval (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 3 blood draws. Evaluable immunogenicity population: eligible subjects who received vaccination as assigned; had blood drawn within pre-specified time-frames; had at least 1 valid, determinate assay result; had no major protocol violation, n = subjects evaluable for specified serotype.	
End point type	Primary
End point timeframe: Before 13vPnC Dose 1 (pre-vaccination), 1 month after 13vPnC Dose 3	

#### Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this end point.

End point values	13vPnC, 23vPS (All Subjects)			
Subject group type	Subject analysis set			
Number of subjects analysed	247 <sup>[2]</sup>			
Units: Fold rise				
geometric mean (confidence interval 95%)				
Serotype 1 (n=191)	17.96 (13.63 to 23.66)			
Serotype 3 (n=192)	5.07 (3.98 to 6.46)			

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
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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
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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 <sup>[3]</sup>	149 <sup>[4]</sup>	198 <sup>[5]</sup>	
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
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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
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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 <sup>[6]</sup>	124 <sup>[7]</sup>	162 <sup>[8]</sup>	
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
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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
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End point timeframe:

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

<b>End point values</b>	13vPnC, 23vPS (Pediatric Subjects)	13vPnC, 23vPS (Adult Subjects)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49 <sup>[9]</sup>	148 <sup>[10]</sup>		
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
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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 <sup>[11]</sup>	123 <sup>[12]</sup>	161 <sup>[13]</sup>	
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
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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 <sup>[14]</sup>	121 <sup>[15]</sup>	157 <sup>[16]</sup>	
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
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### 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 [ $\geq$ ] 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  $\geq$ 12 years); Severe (greater than [ $>$ ] 7.0 cm for subjects aged 2 to  $<$ 12 years and  $>$ 10.0 cm for subjects aged  $\geq$ 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
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### 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 <sup>[17]</sup>	171 <sup>[18]</sup>	223 <sup>[19]</sup>	
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

**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
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## 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  $\geq$ 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  $\geq$ 12 years); Severe  $>$ 7.0 cm for subjects aged 2 to <12 years and  $>$ 10.0 cm for subjects aged  $\geq$ 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
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## 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 <sup>[20]</sup>	157 <sup>[21]</sup>	198 <sup>[22]</sup>	
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
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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
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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 <sup>[23]</sup>	138 <sup>[24]</sup>	175 <sup>[25]</sup>	
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.

## 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 4

End point title	Percentage of Pediatric, Adult and All Subjects Reporting Pre-specified Local Reactions: 13vPnC Dose 4
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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 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	35 <sup>[26]</sup>	116 <sup>[27]</sup>	151 <sup>[28]</sup>	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: any (n = 21, 79, 100)	71.4 (47.8 to 88.7)	22.8 (14.1 to 33.6)	33 (23.9 to 43.1)	
Redness: mild (n = 20, 77, 97)	50 (27.2 to 72.8)	15.6 (8.3 to 25.6)	22.7 (14.8 to 32.3)	
Redness: moderate (n = 18, 72, 90)	50 (26 to 74)	9.7 (4 to 19)	17.8 (10.5 to 27.3)	
Redness: severe (n = 16, 73, 89)	12.5 (1.6 to 38.3)	4.1 (0.9 to 11.5)	5.6 (1.8 to 12.6)	
Swelling: any (n = 27, 81, 108)	66.7 (46 to 83.5)	28.4 (18.9 to 39.5)	38 (28.8 to 47.8)	
Swelling: mild (n = 21, 79, 100)	38.1 (18.1 to 61.6)	21.5 (13.1 to 32.2)	25 (16.9 to 34.7)	
Swelling: moderate (n = 23, 72, 95)	52.2 (30.6 to 73.2)	6.9 (2.3 to 15.5)	17.9 (10.8 to 27.1)	
Swelling: severe (n = 15, 73, 88)	6.7 (0.2 to 31.9)	4.1 (0.9 to 11.5)	4.5 (1.3 to 11.2)	
Pain: any (n = 30, 113, 143)	86.7 (69.3 to 96.2)	77 (68.1 to 84.4)	79 (71.4 to 85.4)	
Pain: mild (n = 25, 105, 130)	76 (54.9 to 90.6)	71.4 (61.8 to 79.8)	72.3 (63.8 to 79.8)	

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 $\geq 38$ 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 ( $\geq 6$ 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 <sup>[29]</sup>	172 <sup>[30]</sup>	223 <sup>[31]</sup>	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: $\geq 38$ 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: $\geq 38$ , $<38.5$ 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: $\geq 38.5$ , $<39$ 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: $\geq 39$ , $= <40$ 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
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End point description:

Specific systemic events (fever  $\geq 38$  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
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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 <sup>[32]</sup>	146 <sup>[33]</sup>	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
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End point description:

Specific systemic events (fever  $\geq 38$  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 ( $\geq 6$  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
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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 <sup>[34]</sup>	136 <sup>[35]</sup>	178 <sup>[36]</sup>	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: $\geq 38$ 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: $\geq 38$ , $< 38.5$ 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: $\geq 38.5$ , $< 39$ 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: $\geq 39$ , $\leq 40$ 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.

## 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 $\geq 38$ 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 ( $\geq 6$ 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 <sup>[37]</sup>	116 <sup>[38]</sup>	148 <sup>[39]</sup>	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: $\geq 38$ 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: $\geq 38$ , $<38.5$ 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: $\geq 38.5$ , $<39$ 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: $\geq 39$ , $\leq 40$ 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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	0.0
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### Reporting groups

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

<b>Serious adverse events</b>	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 treatment / all	0 / 0	0 / 0	0 / 0
Post transplant lymphoproliferative disorder			
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
Acute lymphocytic leukaemia			
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 / 1	0 / 0
Acute lymphocytic leukaemia recurrent			

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
<b>Ependymoma</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
<b>Mantle cell lymphoma</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
<b>Myelodysplastic syndrome</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
<b>Refractory anaemia with an excess of blasts</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
<b>Chronic myeloid leukaemia</b>			
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
<b>Juvenile chronic myelomonocytic leukaemia</b>			
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
<b>Leukaemia</b>			
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
<b>Acute myeloid leukaemia recurrent</b>			

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
<b>Vascular disorders</b>			
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
<b>General disorders and administration site conditions</b>			
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
<b>Investigations</b>			
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
<b>Injury, poisoning and procedural complications</b>			
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
<b>Cardiac disorders</b>			
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
<b>Nervous system disorders</b>			
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
<b>Blood and lymphatic system disorders</b>			
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
<b>Febrile neutropenia</b>			
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
<b>Leukopenia</b>			
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
<b>Lymphadenitis</b>			
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
<b>Warm type haemolytic anaemia</b>			
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
<b>Gastrointestinal disorders</b>			
<b>Diarrhoea</b>			
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
<b>Pancreatitis</b>			
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
<b>Hernial eventration</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
<b>Pancreatitis acute</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
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
<b>Klebsiella sepsis</b>			
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
<b>Molluscum contagiosum</b>			
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
<b>Pneumonia haemophilus</b>			
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
<b>Post procedural infection</b>			
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
<b>Respiratory syncytial virus infection</b>			
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
<b>Sepsis</b>			
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
<b>Sinusitis</b>			
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
<b>Staphylococcal infection</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
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	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
<b>Nasopharyngitis</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
<b>Oral herpes</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
<b>Pneumonia pneumococcal</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
<b>Pneumonia pseudomonas aeruginosa</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
<b>Urinary tract infection</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
<b>Viral upper respiratory tract infection</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
<b>H1N1 influenza</b>			
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
<b>Staphylococcal sepsis</b>			

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
<b>Streptococcal sepsis</b>			
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
<b>Device related infection</b>			
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
<b>Thrombophlebitis septic</b>			
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
<b>Varicella</b>			
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
<b>Urinary tract infection bacterial</b>			
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
<b>Bacterial infection</b>			
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
<b>Bronchiolitis</b>			
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
<b>Oral candidiasis</b>			

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
<b>Pseudomonal sepsis</b>			
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
<b>Metabolism and nutrition disorders</b>			
<b>Decreased appetite</b>			
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
<b>Diabetes mellitus</b>			
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
<b>Hypernatraemia</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
<b>Hyperglycaemia</b>			
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

<b>Serious adverse events</b>	23vPS Dose	Follow-up	
<b>Total subjects affected by serious adverse events</b>			
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	
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
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	
<b>Mantle cell lymphoma</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	
<b>Myelodysplastic syndrome</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	
<b>Refractory anaemia with an excess of blasts</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	
<b>Chronic myeloid leukaemia</b>			
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	
<b>Juvenile chronic myelomonocytic leukaemia</b>			
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	
<b>Leukaemia</b>			
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	
<b>Acute myeloid leukaemia recurrent</b>			
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	
<b>Vascular disorders</b>			

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	
<b>Leukopenia</b>			
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	
<b>Lymphadenitis</b>			
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	
<b>Warm type haemolytic anaemia</b>			
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	
<b>Gastrointestinal disorders</b>			
<b>Diarrhoea</b>			
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	
<b>Pancreatitis</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	
<b>Hernial eventration</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	
<b>Pancreatitis acute</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	
<b>Gastrointestinal haemorrhage</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	
<b>Hepatobiliary disorders</b>			
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	
<b>Hepatocellular injury</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	
<b>Renal and urinary disorders</b>			
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	
<b>Musculoskeletal and connective tissue disorders</b>			
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	
<b>Molluscum contagiosum</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	
<b>Pneumonia haemophilus</b>			
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	
<b>Post procedural infection</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	
<b>Respiratory syncytial virus infection</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	
<b>Sepsis</b>			
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	
<b>Sinusitis</b>			
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	
<b>Staphylococcal infection</b>			
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	
<b>Cellulitis</b>			

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	
<b>Metabolism and nutrition disorders</b>			
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 %

<b>Non-serious adverse events</b>	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%)
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
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 occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Acute myeloid leukaemia recurrent subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Kaposi's sarcoma subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Anogenital warts subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	1 / 192 (0.52%) 1
<b>Vascular disorders</b>			
Hypertension subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	7 / 247 (2.83%) 7	0 / 192 (0.00%) 0
Hypotension subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	2 / 247 (0.81%) 2	1 / 192 (0.52%) 1
Orthostatic hypotension subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	2 / 247 (0.81%) 2	0 / 192 (0.00%) 0
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 2	0 / 192 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Hypovolaemic shock subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Vasodilatation subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Venous insufficiency subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0

Venous thrombosis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Vena cava thrombosis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	3 / 221 (1.36%) 4	15 / 247 (6.07%) 17	3 / 192 (1.56%) 3
Pyrexia subjects affected / exposed occurrences (all)	5 / 221 (2.26%) 5	16 / 247 (6.48%) 17	3 / 192 (1.56%) 3
Oedema peripheral subjects affected / exposed occurrences (all)	6 / 221 (2.71%) 6	12 / 247 (4.86%) 12	0 / 192 (0.00%) 0
Asthenia subjects affected / exposed occurrences (all)	2 / 221 (0.90%) 2	10 / 247 (4.05%) 10	1 / 192 (0.52%) 1
Injection site swelling subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	4 / 247 (1.62%) 4	3 / 192 (1.56%) 4
Injection site erythema subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	3 / 247 (1.21%) 3	4 / 192 (2.08%) 5
Oedema subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	3 / 247 (1.21%) 3	0 / 192 (0.00%) 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 occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Vaccination site oedema subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Vaccination site rash subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Hernia subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 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 <sup>[1]</sup> occurrences (all)	0 / 221 (0.00%) 0	13 / 169 (7.69%) 13	17 / 96 (17.71%) 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 <sup>[2]</sup> occurrences (all)	0 / 221 (0.00%) 0	10 / 167 (5.99%) 10	12 / 92 (13.04%) 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 <sup>[3]</sup> occurrences (all)	0 / 221 (0.00%) 0	2 / 165 (1.21%) 2	5 / 90 (5.56%) 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 <sup>[4]</sup> occurrences (all)	0 / 221 (0.00%) 0	3 / 167 (1.80%) 3	2 / 87 (2.30%) 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 <sup>[5]</sup> occurrences (all)	0 / 221 (0.00%) 0	77 / 157 (49.04%) 77	0 / 192 (0.00%) 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 <sup>[6]</sup> occurrences (all)	0 / 221 (0.00%) 0	42 / 137 (30.66%) 42	0 / 192 (0.00%) 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 <sup>[7]</sup> occurrences (all)	0 / 221 (0.00%) 0	8 / 120 (6.67%) 8	0 / 192 (0.00%) 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 <sup>[8]</sup> occurrences (all)	0 / 221 (0.00%) 0	53 / 142 (37.32%) 53	0 / 192 (0.00%) 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 <sup>[9]</sup> occurrences (all)	0 / 221 (0.00%) 0	44 / 138 (31.88%) 44	0 / 192 (0.00%) 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 <sup>[10]</sup> occurrences (all)	0 / 221 (0.00%) 0	21 / 122 (17.21%) 21	0 / 192 (0.00%) 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 <sup>[11]</sup> occurrences (all)	0 / 221 (0.00%) 0	4 / 119 (3.36%) 4	0 / 192 (0.00%) 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 <sup>[12]</sup> occurrences (all)	0 / 221 (0.00%) 0	13 / 120 (10.83%) 13	0 / 192 (0.00%) 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 <sup>[13]</sup> occurrences (all)	0 / 221 (0.00%) 0	6 / 119 (5.04%) 6	0 / 192 (0.00%) 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 <sup>[14]</sup> occurrences (all)	0 / 221 (0.00%) 0	8 / 117 (6.84%) 8	0 / 192 (0.00%) 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 <sup>[15]</sup> occurrences (all)	0 / 221 (0.00%) 0	30 / 130 (23.08%) 30	0 / 192 (0.00%) 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 <sup>[16]</sup> occurrences (all)	0 / 221 (0.00%) 0	26 / 128 (20.31%) 26	0 / 192 (0.00%) 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 <sup>[17]</sup> occurrences (all)	0 / 221 (0.00%) 0	6 / 119 (5.04%) 6	0 / 192 (0.00%) 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 <sup>[18]</sup> occurrences (all)	0 / 221 (0.00%) 0	2 / 117 (1.71%) 2	0 / 192 (0.00%) 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 <sup>[19]</sup> occurrences (all)	0 / 221 (0.00%) 0	61 / 152 (40.13%) 61	0 / 192 (0.00%) 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 <sup>[20]</sup> occurrences (all)	0 / 221 (0.00%) 0	47 / 142 (33.10%) 47	0 / 192 (0.00%) 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 <sup>[21]</sup> occurrences (all)	0 / 221 (0.00%) 0	27 / 132 (20.45%) 27	0 / 192 (0.00%) 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 <sup>[22]</sup> occurrences (all)	0 / 221 (0.00%) 0	4 / 118 (3.39%) 4	0 / 192 (0.00%) 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 <sup>[23]</sup> occurrences (all)	0 / 221 (0.00%) 0	28 / 132 (21.21%) 28	0 / 192 (0.00%) 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 <sup>[24]</sup> occurrences (all)	0 / 221 (0.00%) 0	23 / 128 (17.97%) 23	0 / 192 (0.00%) 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 <sup>[25]</sup> occurrences (all)	0 / 221 (0.00%) 0	13 / 122 (10.66%) 13	0 / 192 (0.00%) 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 <sup>[26]</sup> occurrences (all)	0 / 221 (0.00%) 0	4 / 119 (3.36%) 4	0 / 192 (0.00%) 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 <sup>[27]</sup> occurrences (all)	0 / 221 (0.00%) 0	13 / 131 (9.92%) 13	0 / 192 (0.00%) 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 <sup>[28]</sup>	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 <sup>[29]</sup>	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 <sup>[30]</sup>	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 <sup>[31]</sup>	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 <sup>[32]</sup>	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 <sup>[33]</sup>	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 <sup>[34]</sup>	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 <sup>[35]</sup>	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 <sup>[36]</sup>	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 <sup>[37]</sup>	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 <sup>[38]</sup>	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 <sup>[39]</sup>	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 <sup>[40]</sup>	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 <sup>[41]</sup>	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 <sup>[42]</sup>	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 <sup>[43]</sup> occurrences (all)	0 / 221 (0.00%)  0	84 / 189 (44.44%)  84	53 / 114 (46.49%)  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 <sup>[44]</sup> occurrences (all)	0 / 221 (0.00%)  0	71 / 186 (38.17%)  71	44 / 109 (40.37%)  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 <sup>[45]</sup> occurrences (all)	0 / 221 (0.00%)  0	31 / 174 (17.82%)  31	26 / 98 (26.53%)  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 <sup>[46]</sup> occurrences (all)	0 / 221 (0.00%)  0	6 / 167 (3.59%)  4	6 / 90 (6.67%)  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 <sup>[47]</sup> occurrences (all)	0 / 221 (0.00%)  0	53 / 152 (34.87%)  53	0 / 192 (0.00%)  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 <sup>[48]</sup> occurrences (all)	0 / 221 (0.00%)  0	44 / 147 (29.93%)  44	0 / 192 (0.00%)  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 <sup>[49]</sup> occurrences (all)	0 / 221 (0.00%)  0	20 / 136 (14.71%)  0	0 / 192 (0.00%)  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 <sup>[50]</sup>	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 <sup>[51]</sup>	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 <sup>[52]</sup>	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 <sup>[53]</sup>	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 <sup>[54]</sup>	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 <sup>[55]</sup>	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 <sup>[56]</sup>	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 <sup>[57]</sup> occurrences (all)	0 / 221 (0.00%) 0	9 / 131 (6.87%) 9	0 / 192 (0.00%) 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 <sup>[58]</sup> occurrences (all)	0 / 221 (0.00%) 0	1 / 126 (0.79%) 1	0 / 192 (0.00%) 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 <sup>[59]</sup> occurrences (all)	0 / 221 (0.00%) 0	66 / 189 (34.92%) 66	29 / 101 (28.71%) 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 <sup>[60]</sup> occurrences (all)	0 / 221 (0.00%) 0	62 / 186 (33.33%) 62	28 / 100 (28.00%) 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 <sup>[61]</sup> occurrences (all)	0 / 221 (0.00%) 0	14 / 171 (8.19%) 14	3 / 87 (3.45%) 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 <sup>[62]</sup> occurrences (all)	0 / 221 (0.00%) 0	5 / 168 (2.98%) 5	1 / 87 (1.15%) 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 <sup>[63]</sup> occurrences (all)	0 / 221 (0.00%) 0	44 / 150 (29.33%) 44	0 / 192 (0.00%) 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 <sup>[64]</sup> occurrences (all)	0 / 221 (0.00%) 0	41 / 149 (27.52%) 41	0 / 192 (0.00%) 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 <sup>[65]</sup>	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 <sup>[66]</sup>	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 <sup>[67]</sup>	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 <sup>[68]</sup>	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 <sup>[69]</sup>	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 <sup>[70]</sup>	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 <sup>[71]</sup>	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 <sup>[72]</sup>	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 <sup>[73]</sup>	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 <sup>[74]</sup>	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 <sup>[75]</sup>	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 <sup>[76]</sup>	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 <sup>[77]</sup>	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 <sup>[78]</sup>	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 <sup>[79]</sup> occurrences (all)	0 / 221 (0.00%) 0	37 / 147 (25.17%) 37	0 / 192 (0.00%) 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 <sup>[80]</sup> occurrences (all)	0 / 221 (0.00%) 0	30 / 142 (21.13%) 30	0 / 192 (0.00%) 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 <sup>[81]</sup> occurrences (all)	0 / 221 (0.00%) 0	20 / 136 (14.71%) 20	0 / 192 (0.00%) 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 <sup>[82]</sup> occurrences (all)	0 / 221 (0.00%) 0	3 / 129 (2.33%) 3	0 / 192 (0.00%) 0
Immune system disorders			
Graft versus host disease subjects affected / exposed occurrences (all)	8 / 221 (3.62%) 9	21 / 247 (8.50%) 24	2 / 192 (1.04%) 2
Chronic graft versus host disease subjects affected / exposed occurrences (all)	3 / 221 (1.36%) 3	12 / 247 (4.86%) 14	0 / 192 (0.00%) 0
Graft versus host disease in liver subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	5 / 247 (2.02%) 7	0 / 192 (0.00%) 0
Graft versus host disease in skin subjects affected / exposed occurrences (all)	6 / 221 (2.71%) 7	4 / 247 (1.62%) 4	0 / 192 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	2 / 247 (0.81%) 3	1 / 192 (0.52%) 1
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	2 / 247 (0.81%) 2	0 / 192 (0.00%) 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
<b>Injury, poisoning and procedural complications</b>			
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 occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Rib fracture subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	1 / 192 (0.52%) 1
Arthropod bite subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Anaemia postoperative subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
<b>Congenital, familial and genetic disorders</b>			
Myotonic dystrophy subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Ichthyosis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
<b>Cardiac disorders</b>			
Palpitations subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	2 / 247 (0.81%) 2	0 / 192 (0.00%) 0
Arrhythmia subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Atrial thrombosis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Dilatation ventricular subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Myocardial infarction subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 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 occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Tympanic membrane disorder subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Deafness neurosensory subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Deafness unilateral subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Ear pruritus subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Eye disorders			
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	6 / 247 (2.43%) 7	0 / 192 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	3 / 221 (1.36%) 3	5 / 247 (2.02%) 5	1 / 192 (0.52%) 1
Allergic keratitis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Conjunctival hyperaemia subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Diabetic retinopathy subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Eye haemorrhage			

subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Keratitis			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Orbital oedema			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Visual acuity reduced			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
Vitreous detachment			
subjects affected / exposed	2 / 221 (0.90%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
Blindness			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
Eye inflammation			

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
<b>Gastrointestinal disorders</b>			
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

Sensitivity of teeth subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	1 / 192 (0.52%) 1
Gastrointestinal disorder subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Inguinal hernia subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	0 / 247 (0.00%) 0	0 / 192 (0.00%) 0
Hepatobiliary disorders			
Hepatic function abnormal subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	3 / 247 (1.21%) 3	0 / 192 (0.00%) 0
Hepatocellular injury subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	1 / 247 (0.40%) 1	0 / 192 (0.00%) 0
Cholestasis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	5 / 247 (2.02%) 6	0 / 192 (0.00%) 0
Skin and subcutaneous tissue disorders			
Rash subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	14 / 247 (5.67%) 14	2 / 192 (1.04%) 2
Pruritus subjects affected / exposed occurrences (all)	2 / 221 (0.90%) 2	11 / 247 (4.45%) 13	1 / 192 (0.52%) 1
Dry skin subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	5 / 247 (2.02%) 5	0 / 192 (0.00%) 0
Eczema			

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

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
<b>Angioedema</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
<b>Intertrigo</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
<b>Pruritus generalised</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
<b>Urticaria</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
<b>Alopecia</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
<b>Redness (Any) : 13vPnC Dose 1 and Dose 4</b>	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 <sup>[83]</sup>	0 / 221 (0.00%)	23 / 168 (13.69%)	33 / 100 (33.00%)
occurrences (all)	0	23	33
<b>Redness (Mild): 13vPnC Dose 1 and Dose 4</b>	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 <sup>[84]</sup>	0 / 221 (0.00%)	20 / 168 (11.90%)	22 / 97 (22.68%)
occurrences (all)	0	20	22
<b>Redness (Moderate): 13vPnC Dose 1 and Dose 4</b>	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 <sup>[85]</sup>	0 / 221 (0.00%)	6 / 165 (3.64%)	16 / 90 (17.78%)
occurrences (all)	0	6	16
<b>Redness (Severe): 13vPnC Dose 1 and Dose 4</b>	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 <sup>[86]</sup>	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 <sup>[87]</sup>	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 <sup>[88]</sup>	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 <sup>[89]</sup>	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 <sup>[90]</sup>	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 <sup>[91]</sup>	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 <sup>[92]</sup>	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 <sup>[93]</sup>	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 <sup>[94]</sup> occurrences (all)	0 / 221 (0.00%) 0	5 / 166 (3.01%) 5	6 / 90 (6.67%) 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 <sup>[95]</sup> occurrences (all)	0 / 221 (0.00%) 0	30 / 137 (21.90%) 30	0 / 192 (0.00%) 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 <sup>[96]</sup> occurrences (all)	0 / 221 (0.00%) 0	26 / 134 (19.40%) 26	0 / 192 (0.00%) 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 <sup>[97]</sup> occurrences (all)	0 / 221 (0.00%) 0	9 / 129 (6.98%) 9	0 / 192 (0.00%) 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 <sup>[98]</sup> occurrences (all)	0 / 221 (0.00%) 0	2 / 127 (1.57%) 2	0 / 192 (0.00%) 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 <sup>[99]</sup> occurrences (all)	0 / 221 (0.00%) 0	25 / 133 (18.80%) 25	0 / 192 (0.00%) 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 <sup>[100]</sup> occurrences (all)	0 / 221 (0.00%) 0	19 / 131 (14.50%) 19	0 / 192 (0.00%) 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 <sup>[101]</sup>	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 <sup>[102]</sup>	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 <sup>[103]</sup>	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 <sup>[104]</sup>	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 <sup>[105]</sup>	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 <sup>[106]</sup>	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 <sup>[107]</sup>	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 <sup>[108]</sup> occurrences (all)	0 / 221 (0.00%) 0	6 / 117 (5.13%) 6	0 / 192 (0.00%) 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 <sup>[109]</sup> occurrences (all)	0 / 221 (0.00%) 0	2 / 116 (1.72%) 2	0 / 192 (0.00%) 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 <sup>[110]</sup> occurrences (all)	0 / 221 (0.00%) 0	18 / 121 (14.88%) 18	0 / 192 (0.00%) 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 <sup>[111]</sup> occurrences (all)	0 / 221 (0.00%) 0	15 / 120 (12.50%) 15	0 / 192 (0.00%) 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 <sup>[112]</sup> occurrences (all)	0 / 221 (0.00%) 0	5 / 117 (4.27%) 5	0 / 192 (0.00%) 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 <sup>[113]</sup> occurrences (all)	0 / 221 (0.00%) 0	1 / 115 (0.87%) 1	0 / 192 (0.00%) 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 <sup>[114]</sup> occurrences (all)	0 / 221 (0.00%) 0	127 / 175 (72.57%) 127	0 / 192 (0.00%) 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 <sup>[115]</sup> occurrences (all)	0 / 221 (0.00%) 0	109 / 163 (66.87%) 109	0 / 192 (0.00%) 0

Pain (Moderate): 13vPnC Dose 3  alternative assessment type: Systematic subjects affected / exposed <sup>[116]</sup> occurrences (all)	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.		
	0 / 221 (0.00%) 0	42 / 141 (29.79%) 42	0 / 192 (0.00%) 0
Pain (Severe): 13vPnC Dose 3  alternative assessment type: Systematic subjects affected / exposed <sup>[117]</sup> occurrences (all)	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.		
	0 / 221 (0.00%) 0	5 / 117 (4.27%) 5	0 / 192 (0.00%) 0
Fatigue (Mild): 13vPnC Dose 3  alternative assessment type: Systematic subjects affected / exposed <sup>[118]</sup> occurrences (all)	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.		
	0 / 221 (0.00%) 0	58 / 148 (39.19%) 58	0 / 192 (0.00%) 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 occurrences (all)	3 / 221 (1.36%) 4	10 / 247 (4.05%) 12	1 / 192 (0.52%) 1
Upper respiratory tract infection subjects affected / exposed occurrences (all)	6 / 221 (2.71%) 8	10 / 247 (4.05%) 12	3 / 192 (1.56%) 3
Herpes zoster subjects affected / exposed occurrences (all)	5 / 221 (2.26%) 5	8 / 247 (3.24%) 11	0 / 192 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	3 / 221 (1.36%) 3	6 / 247 (2.43%) 6	1 / 192 (0.52%) 1
Sinusitis subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	5 / 247 (2.02%) 6	0 / 192 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	5 / 247 (2.02%) 5	1 / 192 (0.52%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 221 (0.90%) 2	4 / 247 (1.62%) 5	0 / 192 (0.00%) 0
Oral fungal infection subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	4 / 247 (1.62%) 4	0 / 192 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	3 / 221 (1.36%) 3	4 / 247 (1.62%) 4	0 / 192 (0.00%) 0
Escherichia infection subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	2 / 247 (0.81%) 3	0 / 192 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 221 (0.00%) 0	2 / 247 (0.81%) 3	0 / 192 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	1 / 221 (0.45%) 1	2 / 247 (0.81%) 3	0 / 192 (0.00%) 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%)
occurrences (all)	0	0	0
Trichosporon infection			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	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
<b>Hypophosphataemia</b>			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
<b>Metabolic acidosis</b>			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
<b>Vitamin D deficiency</b>			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
<b>Vitamin K deficiency</b>			
subjects affected / exposed	0 / 221 (0.00%)	1 / 247 (0.40%)	0 / 192 (0.00%)
occurrences (all)	0	1	0
<b>Hyperkalaemia</b>			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	2	0	0
<b>Glucose tolerance impaired</b>			
subjects affected / exposed	1 / 221 (0.45%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	1	0	0
<b>Haemochromatosis</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
<b>Hypomagnesaemia</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	1 / 192 (0.52%)
occurrences (all)	0	0	1
<b>Hyperlipidaemia</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0
<b>Hypertriglyceridaemia</b>			
subjects affected / exposed	0 / 221 (0.00%)	0 / 247 (0.00%)	0 / 192 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	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
<b>Injection site erythema</b>		
subjects affected / exposed	5 / 184 (2.72%)	0 / 247 (0.00%)
occurrences (all)	5	0
<b>Oedema</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Chest pain</b>		
subjects affected / exposed	0 / 184 (0.00%)	1 / 247 (0.40%)
occurrences (all)	0	1
<b>Catheter site rash</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Chest discomfort</b>		
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)
occurrences (all)	1	0
<b>Complication of device removal</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Feeling cold</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Feeling hot</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Gait disturbance</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Influenza like illness</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Injection site movement impairment</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Injection site pain</b>		

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 occurrences (all)	5 / 184 (2.72%) 5	0 / 247 (0.00%) 0	
Vaccination site swelling subjects affected / exposed occurrences (all)	4 / 184 (2.17%) 4	0 / 247 (0.00%) 0	
Injection site induration subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Injection site inflammation subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Vaccination site oedema subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Vaccination site rash subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Hernia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	1 / 247 (0.40%) 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 <sup>[1]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[2]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[3]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[4]</sup>	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 <sup>[5]</sup>	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 <sup>[6]</sup>	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 <sup>[7]</sup>	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 <sup>[8]</sup>	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 <sup>[9]</sup>	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 <sup>[10]</sup>	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 <sup>[11]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[12]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[13]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[14]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[15]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[16]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[17]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[18]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[19]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[20]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[21]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[22]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[23]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[24]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[25]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[26]</sup>	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 <sup>[27]</sup>	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 <sup>[28]</sup>	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 <sup>[29]</sup>	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 <sup>[30]</sup>	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 <sup>[31]</sup>	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 <sup>[32]</sup>	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 <sup>[33]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[34]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[35]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[36]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[37]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[38]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[39]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[40]</sup>	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 <sup>[41]</sup>	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 <sup>[42]</sup>	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 <sup>[43]</sup>	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 <sup>[44]</sup>	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 <sup>[45]</sup>	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 <sup>[46]</sup>	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 <sup>[47]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[48]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[49]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[50]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[51]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[52]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[53]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[54]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[55]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[56]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[57]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[58]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[59]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[60]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[61]</sup> occurrences (all)	0 / 184 (0.00%)  0	0 / 247 (0.00%)  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 <sup>[62]</sup>	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 <sup>[63]</sup>	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 <sup>[64]</sup>	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 <sup>[65]</sup>	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 <sup>[66]</sup>	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 <sup>[67]</sup>	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 <sup>[68]</sup>	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 <sup>[69]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[70]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[71]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[72]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[73]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[74]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[75]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[76]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	

<p>Joint pain (Moderate): 13vPnC Dose 1 and Dose 4</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[77]</sup></p> <p>occurrences (all)</p>	<p>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.</p>	
	<p>0 / 184 (0.00%)</p> <p>0</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
<p>Joint pain (Severe): 13vPnC Dose 1 and Dose 4</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[78]</sup></p> <p>occurrences (all)</p>	<p>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.</p>	
	<p>0 / 184 (0.00%)</p> <p>0</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
<p>Joint pain (Any): 13vPnC Dose 2</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[79]</sup></p> <p>occurrences (all)</p>	<p>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.</p>	
	<p>0 / 184 (0.00%)</p> <p>0</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
<p>Joint pain (Mild): 13vPnC Dose 2</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[80]</sup></p> <p>occurrences (all)</p>	<p>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.</p>	
	<p>0 / 184 (0.00%)</p> <p>0</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
<p>Joint pain (Moderate): 13vPnC Dose 2</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[81]</sup></p> <p>occurrences (all)</p>	<p>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.</p>	
	<p>0 / 184 (0.00%)</p> <p>0</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
<p>Joint pain (Severe): 13vPnC Dose 2</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed<sup>[82]</sup></p> <p>occurrences (all)</p>	<p>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.</p>	
	<p>0 / 184 (0.00%)</p> <p>0</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
<p>Immune system disorders</p> <p>Graft versus host disease</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Chronic graft versus host disease</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>4 / 184 (2.17%)</p> <p>4</p>	<p>0 / 247 (0.00%)</p> <p>0</p>
	<p>3 / 184 (1.63%)</p> <p>3</p>	<p>0 / 247 (0.00%)</p> <p>0</p>

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

subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Prostatitis			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Genital discharge			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Amenorrhoea			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed occurrences (all)	7 / 184 (3.80%) 7	2 / 247 (0.81%) 2	
Dyspnoea exertional			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Rhinorrhoea			
subjects affected / exposed occurrences (all)	3 / 184 (1.63%) 3	0 / 247 (0.00%) 0	
Lung disorder			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Lung infiltration			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Oropharyngeal plaque			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Productive cough			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Body temperature increased subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Transaminases increased subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Injury, poisoning and procedural complications			
Transfusion reaction subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Laceration subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Ligament sprain subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Eye injury subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Fall subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Febrile nonhaemolytic transfusion reaction subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Infusion related reaction			

subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Conjunctival scar subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Drug administration error subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Post-traumatic pain subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Procedural pain subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Rib fracture subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Arthropod bite subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Anaemia postoperative subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	1 / 247 (0.40%) 1	
<b>Congenital, familial and genetic disorders</b>			
Myotonic dystrophy subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Ichthyosis subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
<b>Cardiac disorders</b>			
Palpitations subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Hyperaesthesia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Myoclonus subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Nervous system disorder subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Blood and lymphatic system disorders			
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Eosinophilia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	1 / 247 (0.40%) 1	
Anaemia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Aplasia pure red cell subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Anaemia macrocytic subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Aplastic anaemia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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
Gastroesophageal 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 occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Abdominal distension subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Oral lichen planus subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Odynophagia subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Sensitivity of teeth subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Gastrointestinal disorder subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Inguinal hernia subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Hepatobiliary disorders			
Hepatic function abnormal subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Hepatocellular injury subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Cholestasis			

subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Skin and subcutaneous tissue disorders</b>			
<b>Rash</b>			
subjects affected / exposed occurrences (all)	2 / 184 (1.09%) 2	0 / 247 (0.00%) 0	
<b>Pruritus</b>			
subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
<b>Dry skin</b>			
subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
<b>Eczema</b>			
subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
<b>Erythema</b>			
subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
<b>Skin lesion</b>			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Acne</b>			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Rash macular</b>			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Rash papular</b>			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Blister</b>			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Dermatitis acneiform</b>			
subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	

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 <sup>[83]</sup>	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 <sup>[84]</sup>	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 <sup>[85]</sup>	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 <sup>[86]</sup>	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 <sup>[87]</sup>	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 <sup>[88]</sup>	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 <sup>[89]</sup>	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 <sup>[90]</sup>	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 <sup>[91]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[92]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[93]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[94]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[95]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[96]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[97]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[98]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[99]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[100]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[101]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[102]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[103]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[104]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[105]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[106]</sup>	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 <sup>[107]</sup>	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 <sup>[108]</sup>	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 <sup>[109]</sup>	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 <sup>[110]</sup>	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 <sup>[111]</sup>	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 <sup>[112]</sup>	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 <sup>[113]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[114]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[115]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[116]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[117]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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 <sup>[118]</sup> occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Renal and urinary disorders			
Polyuria subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Renal failure subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Dysuria subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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
<b>Bone pain</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Flank pain</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Joint stiffness</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Muscular weakness</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Myopathy</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Osteonecrosis</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Osteoporosis</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Synovial cyst</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Groin pain</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Osteopenia</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Spinal osteoarthritis</b>		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
<b>Tendonitis</b>		

subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Sjogren's syndrome subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
<b>Infections and infestations</b>			
Nasopharyngitis subjects affected / exposed occurrences (all)	9 / 184 (4.89%) 9	0 / 247 (0.00%) 0	
Cytomegalovirus infection subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 184 (1.63%) 3	1 / 247 (0.40%) 1	
Herpes zoster subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	2 / 247 (0.81%) 2	
Bronchitis subjects affected / exposed occurrences (all)	2 / 184 (1.09%) 2	1 / 247 (0.40%) 1	
Sinusitis subjects affected / exposed occurrences (all)	2 / 184 (1.09%) 2	0 / 247 (0.00%) 0	
Tonsillitis subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	1 / 247 (0.40%) 1	
Oral fungal infection subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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)	3	0
Oral herpes		
subjects affected / exposed	1 / 184 (0.54%)	0 / 247 (0.00%)
occurrences (all)	1	0
Candidiasis		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
Enterobacter sepsis		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
Escherichia sepsis		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
Eye infection		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0
Otitis media		
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)
occurrences (all)	2	0
Pharyngitis		
subjects affected / exposed	2 / 184 (1.09%)	0 / 247 (0.00%)
occurrences (all)	2	0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 184 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	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 occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Injection site cellulitis subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	0 / 247 (0.00%) 0	
Trichosporon infection subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	1 / 247 (0.40%) 1	
Rash pustular subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	1 / 247 (0.40%) 1	
Fluid retention subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	3 / 184 (1.63%) 3	0 / 247 (0.00%) 0	
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 0	
Cachexia subjects affected / exposed occurrences (all)	0 / 184 (0.00%) 0	0 / 247 (0.00%) 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:

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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

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

Justification:

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













[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:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported