Clinical trial results:
A Phase 4, Randomized, Placebo-Controlled Clinical Trial of 13-valent Pneumococcal Conjugate Vaccine Efficacy in Prevention of Vaccine-Serotype Pneumococcal Community-Acquired Pneumonia and Invasive Pneumococcal Disease

Summary

EudraCT number	2008-000023-26
Trial protocol	NL
Global end of trial date	01 October 2013

Results information

Result version number	v1 (current)
This version publication date	14 August 2016
First version publication date	14 August 2016

Trial information

Trial identification

Sponsor protocol code	6115A1-3006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00744263
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1851025

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 May 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the efficacy of 13 -valent Pneumococcal Conjugate Vaccine (vPnC) in the prevention of a first episode of confirmed vaccine type (VT) pneumococcal community-acquired pneumonia (CAP).

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 Council 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	15 September 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 84496
Worldwide total number of subjects	84496
EEA total number of subjects	84496

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	6
From 65 to 84 years	81547

85 years and over	2943

Subject disposition

Recruitment

Recruitment details:

Of 84496 subjects who were randomized in this study, 2011 subjects were included in the immunogenicity subset. Subjects in the immunogenicity subset were analyzed for local reactions and systemic events as per planned analysis.

Pre-assignment

Screening details:

Of the 87,590 subjects screened, 42,240 subjects received 13vPnC, 42,256 subjects received placebo, and 3094 subjects were screened but not enrolled.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC

Arm description:

Subjects received a single 0.5 milliliter (mL) dose of 13-vPnC intramuscular injection on Day 1.

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

Dosage and administration details:

Subjects received a single 0.5 milliliter (mL) dose of 13-valent pneumococcal conjugate vaccine (13vPnC) intramuscular injection on Day 1.

Arm title	Placebo

Arm description:

Subjects received placebo matched to a single dose of 13vPnC intramuscular injection on Day 1.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received placebo matched to a single dose of 13vPnC intramuscular injection on Day 1.

Number of subjects in period 1	13vPnC	Placebo
Started	42240	42256
Completed	37004	36936
Not completed	5236	5320
Consent withdrawn by subject	166	150
Physician decision	20	23
Adverse Event	1	-
Death	3006	3005
Unspecified	2	2
Lost to follow-up	2038	2135
Protocol deviation	3	5

Baseline characteristics

Reporting groups	
Reporting group title	13vPnC
Reporting group description:	
Subjects received a single 0.5 milliliter (mL) dose of 13-vPnC intramuscular injection on Day 1.	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to a single dose of 13vPnC intramuscular injection on Day 1.	

Reporting group values	13vPnC	Placebo	Total
Number of subjects	42240	42256	84496
Age Categorical Units: Subjects			
Adults (18-64 years)	3	3	6
From 65-84 years	40733	40814	81547
85 years and over	1504	1439	2943
Age Continuous Units: years			
arithmetic mean	72.8	72.8	
standard deviation	± 5.7	± 5.6	-
Gender Categorical Units: Subjects			
Female	18790	18454	37244
Male	23450	23802	47252

End points

End points reporting groups

Reporting group title	13vPnC
Reporting group description:	
Subjects received a single 0.5 milliliter (mL) dose of 13-vPnC intramuscular injection on Day 1.	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to a single dose of 13vPnC intramuscular injection on Day 1.	

Primary: Number of Subjects With First Episode of Confirmed Vaccine-type Community-acquired Pneumonia (VT-CAP)

End point title	Number of Subjects With First Episode of Confirmed Vaccine-type Community-acquired Pneumonia (VT-CAP)

End point description:

CAP was based on clinical and radiological criteria. Clinical criteria:presence of 2 or more criteria:cough,production or change in sputum character,temperature greater than(>)38.0 or less than(<)36.1 degrees Celsius,auscultatory findings consistent with pneumonia including rales/evidence of pulmonary consolidation,leukocytosis(>10*10^9 white blood cells/liter or >15 percent bands),C-reactive protein level >3 times upper limit of normal,hypoxemia with partial oxygen pressure <60 millimeter of mercury. Radiological criteria: pneumonia confirmed by adjudication committee via lateral,posterior-anterior chest x-ray/anterior-posterior chest x-ray. Microbiological criteria: VT Streptococcus pneumonia culture from blood,pleural fluid or other sterile site or positive VT serotype-specific urinary antigen detection(SSUAD). Per-protocol population: subjects with CAP/invasive pneumococcal disease(IPD);symptom onset at least 14 days after vaccination;immunocompetent;no

End point type	Primary

End point timeframe:

Baseline up to occurrence of first episode of VT-CAP, death, withdrawal of consent, loss to follow-up, subject request or end of case acquisition defined as accumulation of 130 VT cases (mean follow-up was 3.97 years)

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42240	42256		
Units: subjects				
number (not applicable)	49	90		

Statistical analyses

Statistical analysis title	13vPnC vs Placebo

Statistical analysis description:

Vaccine efficacy = 1 (proportion of subjects who received 13vPnC with confirmed VT-CAP relative to those who received placebo). Confidence intervals were calculated using Clopper-Pearson method after adjusting for one interim analysis using O'Brien-Fleming procedure, with significance level of 0.0052 at the interim analysis and approximately 0.0480 at the final analysis. The null hypothesis was vaccine efficacy = 0.

Comparison groups	13vPnC v Placebo

Number of subjects included in analysis	84496
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	Binomial Exact Test
Parameter estimate	Vaccine Efficacy
Point estimate	45.56
Confidence interval	
level	95.2 %
sides	2-sided
lower limit	21.82
upper limit	62.49

Secondary: Number of Subjects With First Episode of Nonbacteremic/Noninvasive (NB/NI) Vaccine-type Community-acquired Pneumonia (VT-CAP)

End point title	Number of Subjects With First Episode of Nonbacteremic/Noninvasive (NB/NI) Vaccine-type Community-acquired Pneumonia (VT-CAP)

End point description:

CAP was defined based on clinical and radiological criteria. Microbiological criteria differentiate different categories of CAP. Clinical criteria: presence of 2 or more criteria from following: cough, production of purulent sputum/change in sputum character, temperature >38.0 degrees Celsius (C) or <36.1 degrees C, auscultatory findings consistent with pneumonia including rales and/or evidence of pulmonary consolidation, leukocytosis (>10*10^9 white blood cells/liter or >15% bands), C-reactive protein level >3 times upper limit of normal, hypoxemia with partial oxygen pressure <60 mmHg. Radiological criteria: pneumonia confirmation by adjudication committee via lateral, posterior-anterior chest x-ray or anterior-posterior chest x-ray. Microbiological criteria: Confirmed VT pneumococcal CAP (by SSUAD) where a blood culture result was available and was negative and for which any other sterile culture results were negative for Streptococcus pneumoniae. Per Protocol Population.

End point type	Secondary

End point timeframe:

Baseline up to occurrence of first episode of NB/NI VT-CAP, death, withdrawal of consent, loss to follow-up, subject request or end of case acquisition defined as accumulation of 130 VT cases (mean follow-up was 3.97 years)

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42240	42256		
Units: subjects				
number (not applicable)	33	60		

Statistical analyses

Statistical analysis title	13vPnC vs Placebo

Statistical analysis description:

Vaccine efficacy = 1 (proportion of subjects who received 13vPnC with confirmed VT-CAP relative to those who received placebo). Confidence intervals were calculated using Clopper-Pearson method after adjusting for one interim analysis using O'Brien-Fleming procedure, with significance level of 0.0052 at

the interim analysis and approximately 0.0480 at the final analysis. The null hypothesis was vaccine efficacy = 0.

Comparison groups	13vPnC v Placebo
Number of subjects included in analysis	84496
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0067
Method	Binomial Exact Test
Parameter estimate	Vaccine efficacy
Point estimate	45
Confidence interval	
level	95.2 %
sides	2-sided
lower limit	14.21
upper limit	65.31

Secondary: Number of Subjects With First Episodes of Vaccine-type Invasive Pneumococcal Disease (VT-IPD) Cases

End point title	Number of Subjects With First Episodes of Vaccine-type Invasive Pneumococcal Disease (VT-IPD) Cases

End point description:

VT-IPD was defined as the presence of Streptococcus pneumoniae in a sterile site (blood, cerebrospinal fluid, pleural fluid, peritoneal fluid, pericardial fluid, surgical aspirate, bone, or joint fluid). Per-protocol population: subjects with CAP/invasive pneumococcal disease (IPD);symptom onset at least 14 days after vaccination;immunocompetent;no major protocol violations .

End point type	Secondary

End point timeframe:

Baseline up to occurrence of first episode of VT-IPD, death, withdrawal of consent, loss to follow-up, participant request or end of case acquisition defined as accumulation of 130 VT cases (mean follow-up was 3.97 years)

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42240	42256		
Units: subjects				
number (not applicable)	7	28		

Statistical analyses

Statistical analysis title	13vPnC vs Placebo

Statistical analysis description:

Vaccine efficacy = 1 (proportion of subjects who received 13vPnC with confirmed VT-CAP relative to those who received placebo). Confidence intervals were calculated using Clopper-Pearson method after adjusting for one interim analysis using O'Brien-Fleming procedure, with significance level of 0.0052 at the interim analysis and approximately 0.0480 at the final analysis. The null hypothesis was vaccine efficacy = 0.

Comparison groups	13vPnC v Placebo

Number of subjects included in analysis	84496
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005
Method	Binomial Exact Test
Parameter estimate	Vaccine efficacy
Point estimate	75
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.43
upper limit	90.78

Other pre-specified: Percentage of Subjects With Pre-specified Local Reactions Within 7 Days After Vaccination

End point title	Percentage of Subjects With Pre-specified Local Reactions Within 7 Days After Vaccination

End point description:

Local reactions were reported using electronic diary (e-diary). Redness and swelling scaled as Any (redness or swelling present); Absent (no or minimal); Mild (2.5 centimeter [cm] to 5.0 cm); Moderate (5.1 to 10.0 cm); Severe (>10.0 cm). Pain scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Limitation of arm movement scaled as Any (limitation present); Absent (no limitation of arm movement); Mild (some limitation of arm movement); Moderate (unable to move arm above head, but able to move arm above shoulder); Severe (unable to move arm above shoulder). Percentage of subjects with local reactions were reported. Immunogenicity subset: Subjects may be represented in more than 1 category. 'N' (number of participants analyzed) signifies subjects with known values for any local reaction and 'n' signifies subjects with known values for specified local reaction.

End point type	Other pre-specified

End point timeframe:

Within 7 days after vaccination

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	917	867		
Units: percentage of subjects				
number (confidence interval 95%)				
Redness: Any (n = 886, 859)	4.9 (3.5 to 6.5)	1.2 (0.6 to 2.1)		
Redness: Mild (n = 886, 859)	3.7 (2.6 to 5.2)	0.8 (0.3 to 1.7)		
Redness: Moderate (n = 881, 859)	1.7 (1 to 2.8)	0.3 (0.1 to 1)		
Redness: Severe (n = 881, 859)	0.5 (0.1 to 1.2)	0.1 (0 to 0.6)		
Swelling: Any (n = 888, 859)	6.8 (5.2 to 8.6)	1.2 (0.6 to 2.1)		
Swelling: Mild (n = 888, 859)	5.5 (4.1 to 7.2)	0.7 (0.3 to 1.5)		
Swelling: Moderate (n = 884, 859)	2.6 (1.7 to 3.9)	0.6 (0.2 to 1.4)		
Swelling: Severe (n = 881, 859)	0.1 (0 to 0.6)	0.1 (0 to 0.6)		
Pain: Any (n = 914, 863)	36.1 (33 to 39.3)	6.1 (4.6 to 8)		
Pain: Mild (n = 913, 861)	32.9 (29.8 to 36)	5.6 (4.1 to 7.3)		

Pain: Moderate (n = 886, 860)	7.7 (6 to 9.6)	0.6 (0.2 to 1.4)		
Pain: Severe (n = 881, 860)	0.3 (0.1 to 1)	0.1 (0 to 0.6)		
Limitation of arm movement: Any (n = 891, 865)	14.1 (11.9 to 16.6)	3.2 (2.2 to 4.6)		
Limitation of arm movement: Mild (n = 888, 863)	12.4 (10.3 to 14.7)	2.5 (1.6 to 3.8)		
Limitation of arm movement: Moderate (n =883, 860)	1.7 (1 to 2.8)	0.5 (0.1 to 1.2)		
Limitation of arm movement: Severe (n = 882, 861)	1.2 (0.6 to 2.2)	0.7 (0.3 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Pre-specified Systemic Events Within 7 Days After Vaccination

End point title	Percentage of Subjects with Pre-specified Systemic Events Within 7 Days After Vaccination

End point description:

SE(fever,fatigue,headache,chills,rash,vomiting,decreased appetite,diarrhea,new generalized muscle/joint pain[new muscle/joint pain],aggravated generalized muscle/joint pain[aggravated muscle/joint pain],use of medication to treat pain/fever)reported using an e-diary.Fever- Absent[<38 degree (º)C];Mild(greater than or equal to[>=]38to<38.5ºC);Moderate(>=38.5 to <39ºC);Severe(>=39 to less than or equal to[<=]40 ºC);Potentially life threatening (>40 ºC).Fatigue,headache,new/aggravated muscle/joint pain- Mild(no interference);Moderate(some interference);Severe(prevented routine activity).Vomiting- Mild(1-2 times in 24 hours [hrs]);Moderate(>2 times in 24 hrs);Severe(required intravenous hydration).Diarrhea-Mild(2-3 loose stools in 24 hrs);Moderate(4-5 loose stools in 24 hrs);Severe(>=6 loose stools in 24 hrs) % of subjects with SE were reported.Safety population= all subjects who received study vaccine and had any safety data. Population : Immunogenicity subset

End point type	Other pre-specified

End point timeframe:

Within 7 days after vaccination

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	918	907		
Units: percentage of subjects				
number (confidence interval 95%)				
Fever: >=38 to <38.5 degrees C (n = 883, 859)	1.1 (0.5 to 2.1)	0.6 (0.2 to 1.4)		
Fever: >=38.5 to <39 degrees C (n = 881, 859)	0.6 (0.2 to 1.3)	0.2 (0 to 0.8)		
Fever: >=39 to =<40 degrees C (n = 882, 859)	0.7 (0.3 to 1.5)	0.2 (0 to 0.8)		
Fever: >40 degrees C (n = 882, 860)	0.8 (0.3 to 1.6)	0.3 (0.1 to 1)		
Fatigue: Mild (n = 892, 871)	13.8 (11.6 to 16.2)	11.7 (9.7 to 14)		
Fatigue: Moderate (n = 886, 866)	7.8 (6.1 to 9.8)	6.2 (4.7 to 8.1)		
Fatigue: Severe (n = 883, 863)	1.4 (0.7 to 2.4)	0.9 (0.4 to 1.8)		

Headache: Mild (n = 891, 870)	13 (10.9 to 15.4)	13.1 (10.9 to 15.5)		
Headache: Moderate (n = 883, 868)	5.2 (3.8 to 6.9)	3.8 (2.6 to 5.3)		
Headache: Severe (n = 881, 861)	0.6 (0.2 to 1.3)	0.6 (0.2 to 1.3)		
Chills (n = 891, 866)	9.4 (7.6 to 11.5)	8.4 (6.7 to 10.5)		
Rash (n = 882, 860)	3.3 (2.2 to 4.7)	0.8 (0.3 to 1.7)		
Vomiting: Mild (n = 881, 860)	0 (0 to 0.4)	0.7 (0.3 to 1.5)		
Vomiting: Moderate (n =881, 860)	0.1 (0 to 0.6)	0.1 (0 to 0.6)		
Vomiting: Severe (n = 881, 860)	0.2 (0 to 0.8)	0.1 (0 to 0.6)		
Decreased appetite (n = 886, 865)	5.3 (3.9 to 7)	3.7 (2.5 to 5.2)		
Diarrhea: Mild (n = 887, 868)	5.1 (3.7 to 6.7)	7.7 (6 to 9.7)		
Diarrhea: Moderate (n = 882, 863)	1.2 (0.6 to 2.2)	1 (0.5 to 2)		
Diarrhea: Severe (n = 881, 862)	0.7 (0.3 to 1.5)	0.5 (0.1 to 1.2)		
New muscle pain: Mild (n = 894, 865)	14.5 (12.3 to 17)	6.7 (5.1 to 8.6)		
New muscle pain: Moderate (n = 886, 863)	5.9 (4.4 to 7.6)	2.8 (1.8 to 4.1)		
New muscle pain: Severe (n = 882, 860)	0.7 (0.3 to 1.5)	0.5 (0.1 to 1.2)		
Aggravated muscle pain: Mild (n = 886, 862)	4.6 (3.3 to 6.2)	1.9 (1.1 to 3)		
Aggravated muscle pain: Moderate (n = 885, 863)	5.1 (3.7 to 6.7)	2.8 (1.8 to 4.1)		
Aggravated muscle pain: Severe (n = 882, 860)	0.7 (0.3 to 1.5)	0.1 (0 to 0.6)		
New joint pain: Mild (n = 884, 862)	5 (3.6 to 6.6)	3.9 (2.7 to 5.5)		
New joint pain: Moderate (n = 883, 864)	2.9 (1.9 to 4.3)	2.2 (1.3 to 3.4)		
New joint pain: Severe (n = 882, 860)	0.3 (0.1 to 1)	0.3 (0.1 to 1)		
Aggravated joint pain: Mild (n = 883, 861)	2.3 (1.4 to 3.5)	1.7 (1 to 2.9)		
Aggravated joint pain: Moderate (n = 884, 862)	3.2 (2.1 to 4.5)	2.6 (1.6 to 3.8)		
Aggravated joint pain: Severe (n = 882, 860)	0.3 (0.1 to 1)	0.3 (0.1 to 1)		
Use of medication to treat pain (n = 887, 872)	8 (6.3 to 10)	6.2 (4.7 to 8)		
Use of medication to treat fever (n = 883, 863)	3.2 (2.1 to 4.6)	1.5 (0.8 to 2.6)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects Who Died

End point title	Percentage of Subjects Who Died

End point description:

Deaths collected throughout the case acquisition period were presented. Safety population included all subjects who received study vaccine and who had any safety data.

End point type	Other pre-specified

End point timeframe:

From signing of informed consent form up to case acquisition period defined as accumulation of 130 VT cases (mean follow-up was 3.97 years)

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42237	42255		
Units: percentage of subjects				
number (not applicable)	7.1	7.1		

Statistical analyses

Statistical analysis title	13vPnC vs Placebo

Statistical analysis description:

Fisher exact test, 2-sided, was used to calculate the p-value for the difference between vaccine groups in percentages of participants.

Comparison groups	13vPnC v Placebo
Number of subjects included in analysis	84492
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.979
Method	Fisher exact

Other pre-specified: Percentage of Subjects With Newly Diagnosed Chronic Medical Condition

End point title	Percentage of Subjects With Newly Diagnosed Chronic Medical Condition

End point description:

Percentage of subjects with newly diagnosed chronic medical conditions (including autoimmune or neuroinflammatory disease) in the immunogenicity subset were reported as per planned analysis. Immunogenicity subset included participants enrolled in the subset who received study vaccine, were able to complete e-diary and fulfilled other study procedures.

End point type	Other pre-specified

End point timeframe:

From 1 month after vaccination up to 6 months after vaccination

End point values	13vPnC	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1006	1005		
Units: percentage of subjects				
number (not applicable)	1.7	1.2		

Statistical analyses

Statistical analysis title	13vPnC vs Placebo

Statistical analysis description:

Fisher exact test, 2-sided, was used to calculate the p-value for the difference between vaccine groups in percentages of participants.

Comparison groups	13vPnC v Placebo
Number of subjects included in analysis	2011
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.455
Method	Fisher exact

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Safety set (SAEs: Day 1 up to 1 month after vaccination); Immunogenicity subset (SAEs:1 month up to 6 months after vaccination; Other AEs: Day 1 up to 1 month after vaccination; pre-specified local reactions, systemic events:up to 7 days after vaccination

Adverse event reporting additional description:

SAEs were collected up to 1 month after vaccination for safety set. For immunogenicity subset, other AEs were collected up to 1 month after vaccination and SAEs collected from 1 month up to 6 months after vaccination. Deaths collected throughout case acquisition period but reported as SAE only during SAE collection periods as per planned analysis.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	13vPnC Safety Set

Reporting group description:

All subjects who received a single 0.5 milliliter mL dose of 13-vPnC intramuscular injection on Day 1, were assessed for serious adverse events (SAEs) from vaccination up to 1 month after vaccination. Safety set included all subjects who received study vaccine and who had any safety data.

Reporting group title	Placebo Safety Set

Reporting group description:

All subjects who received placebo matched to a single dose of 13vPnC intramuscular injection on Day 1, were assessed for SAEs from vaccination up to 1 month after vaccination. Safety set included all subjects who received study treatment and who had any safety data.

Reporting group title	13vPnC Immunogenicity Subset

Reporting group description:

Subjects included in immunogenicity subset who received a single 0.5 mL dose of 13vPnC intramuscular injection on Day 1, were assessed for SAEs from 1 month after vaccination up to 6 months after vaccination and for other adverse events from vaccination up to 1 month after vaccination. Immunogenicity subset included subjects enrolled in the subset who received study vaccine, were able to complete e-diary and fulfilled other study procedures.

Reporting group title	Placebo Immunogenicity Subset

Reporting group description:

Subjects included in immunogenicity subset who received placebo matched to a single dose of 13vPnC intramuscular injection on Day 1, were assessed for SAEs from 1 month after vaccination up to 6 months after vaccination and for other AEs from vaccination up to 1 month after vaccination. Immunogenicity subset included subjects enrolled in the subset who received study treatment, were able to complete e-diary and fulfilled other study procedures.

Serious adverse events	13vPnC Safety Set	Placebo Safety Set	13vPnC Immunogenicity Subset
Total subjects affected by serious adverse events			
subjects affected / exposed	327 / 42237 (0.77%)	314 / 42255 (0.74%)	55 / 1006 (5.47%)
number of deaths (all causes)	3006	3005	69
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Basal cell carcinoma			
subjects affected / exposed	22 / 42237 (0.05%)	16 / 42255 (0.04%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 22	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	10 / 42237 (0.02%)	7 / 42255 (0.02%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	7 / 42237 (0.02%)	6 / 42255 (0.01%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	2 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	2 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	2 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Gastric cancer			
subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Bladder cancer			

subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Colon cancer metastatic			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Rectal cancer			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Bladder adenocarcinoma stage unspecified			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Bowen's disease			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Bronchial carcinoma			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Colorectal cancer metastatic			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Glioblastoma			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Glioma			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Hepatic adenoma			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Hypopharyngeal cancer			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Laryngeal cancer			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Leukaemia			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Lung neoplasm malignant			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Malignant neoplasm of renal pelvis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Melanoma recurrent			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Mesothelioma			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Metastasis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Metastatic gastric cancer			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Metastatic renal cell carcinoma			

subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Neoplasm prostate			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Oesophageal carcinoma recurrent			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Prostate cancer metastatic			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Prostate cancer recurrent			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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 cell carcinoma			

subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Small cell lung cancer			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Squamous cell carcinoma			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Tonsil cancer			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Bile duct adenocarcinoma			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Colon neoplasm			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer recurrent			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	3 / 42237 (0.01%)	2 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Aortic aneurysm rupture			
subjects affected / exposed	3 / 42237 (0.01%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Hypotension			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Deep vein thrombosis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Haematoma			

subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Intermittent claudication			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Temporal arteritis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Thrombophlebitis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Malignant hypertension			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	12 / 42237 (0.03%)	2 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	5 / 42237 (0.01%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			

subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental death			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Death			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Device occlusion			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Hernia obstructive			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Malaise			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Medical device complication			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Pyrexia			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Implant site fibrosis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Anaphylactic shock			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Corneal graft rejection			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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

Acquired phimosis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	13 / 42237 (0.03%)	8 / 42255 (0.02%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 13	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	3 / 42237 (0.01%)	2 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Sleep apnoea syndrome			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Alveolitis allergic			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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

Hydrothorax			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Lung infiltration			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Epistaxis			
subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Asphyxia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Pleural effusion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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			
Bipolar disorder			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Delirium			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Psychotic disorder			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Suicidal ideation			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Investigations			
Weight decreased			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	5 / 42237 (0.01%)	4 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	3 / 42237 (0.01%)	3 / 42255 (0.01%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	3 / 42237 (0.01%)	2 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 42237 (0.00%)	4 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	2 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Radius fracture			
subjects affected / exposed	1 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ankle fracture			
subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Contusion			
subjects affected / exposed	0 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (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
Head injury			
subjects affected / exposed	1 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Rib fracture			
subjects affected / exposed	3 / 42237 (0.01%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (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
Fracture			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Pelvic fracture			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Ulna fracture			

subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Wrist fracture			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Accidental overdose			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Anaemia postoperative			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Cardiac valve replacement complication			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Concussion			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Facial bones fracture			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Forearm fracture			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Foreign body aspiration			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Incisional hernia			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Joint dislocation			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Kidney contusion			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Ligament injury			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Lower limb fracture			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Mental status changes postoperative			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Multiple injuries			

subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Periprosthetic fracture			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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 laminectomy syndrome			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Procedural intestinal perforation			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Procedural pain			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Tendon injury			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Thermal burn			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Urinary retention postoperative			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Vascular graft occlusion			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Wound dehiscence			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Procedural haemorrhage			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	19 / 42237 (0.04%)	19 / 42255 (0.04%)	3 / 1006 (0.30%)
occurrences causally related to treatment / all	0 / 19	0 / 19	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	13 / 42237 (0.03%)	9 / 42255 (0.02%)	3 / 1006 (0.30%)
occurrences causally related to treatment / all	0 / 13	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	12 / 42237 (0.03%)	6 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	7 / 42237 (0.02%)	10 / 42255 (0.02%)	4 / 1006 (0.40%)
occurrences causally related to treatment / all	0 / 7	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Atrial flutter			
subjects affected / exposed	5 / 42237 (0.01%)	2 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	3 / 42237 (0.01%)	4 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	2 / 42237 (0.00%)	3 / 42255 (0.01%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac asthma			
subjects affected / exposed	2 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	2 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Cardiac arrest			
subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Sick sinus syndrome			
subjects affected / exposed	1 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Aortic valve stenosis			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Atrioventricular block complete			

subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Myocardial ischaemia			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Arrhythmia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Atrial tachycardia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Bradycardia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Cardio-respiratory arrest			

subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Coronary artery dissection			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Left ventricular failure			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Mitral valve incompetence			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Palpitations			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Silent myocardial infarction			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Sinus bradycardia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Atrioventricular block second degree			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Coronary artery stenosis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	9 / 42237 (0.02%)	8 / 42255 (0.02%)	3 / 1006 (0.30%)
occurrences causally related to treatment / all	0 / 9	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	4 / 42237 (0.01%)	9 / 42255 (0.02%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Transient ischaemic attack			
subjects affected / exposed	8 / 42237 (0.02%)	5 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	3 / 42237 (0.01%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			

subjects affected / exposed	2 / 42237 (0.00%)	1 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 42237 (0.00%)	2 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dizziness			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Epilepsy			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Loss of consciousness			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Transient global amnesia			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Acute disseminated encephalomyelitis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Cerebral ischaemia			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Convulsion			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Hemiparesis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Peroneal nerve palsy			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Radicular pain			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Radiculitis lumbosacral			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Trigeminal neuralgia			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Carotid artery stenosis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Ischaemic stroke			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nerve lesion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Iron deficiency anaemia			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Pancytopenia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Vertigo			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Retinal detachment			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Retinal artery occlusion			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Macular fibrosis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ileus			
subjects affected / exposed	2 / 42237 (0.00%)	4 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Constipation			
subjects affected / exposed	4 / 42237 (0.01%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Colitis			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Diarrhoea			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Abdominal pain			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Duodenal perforation			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Duodenal ulcer			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Gastric perforation			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Gastritis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Intestinal obstruction			

subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Intestinal perforation			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Pancreatitis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Subileus			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Varices oesophageal			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Abdominal hernia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
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			
Cholecystitis			
subjects affected / exposed	2 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Bile duct stone			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Cholangitis			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Cholecystitis acute			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Cholelithiasis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Skin and subcutaneous tissue disorders			

Skin ulcer			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Rash			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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			
Calculus bladder			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Haematuria			
subjects affected / exposed	2 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis noninfective			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Nephrolithiasis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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 impairment			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Ureteric stenosis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Urethral stenosis			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Finger deformity			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Intervertebral disc protrusion			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Osteoarthritis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cyst			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Polymyalgia rheumatica			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Spondylolisthesis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
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			
Pneumonia			
subjects affected / exposed	14 / 42237 (0.03%)	6 / 42255 (0.01%)	4 / 1006 (0.40%)
occurrences causally related to treatment / all	0 / 15	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 42237 (0.00%)	4 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	3 / 42237 (0.01%)	2 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 42237 (0.00%)	3 / 42255 (0.01%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 42237 (0.00%)	3 / 42255 (0.01%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 42237 (0.00%)	2 / 42255 (0.00%)	0 / 1006 (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
Diverticulitis			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Pneumonia legionella			
subjects affected / exposed	1 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Wound infection			
subjects affected / exposed	0 / 42237 (0.00%)	2 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Cholangitis suppurative			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Cystitis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Erysipelas			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Peritonitis			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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 tract infection			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Tuberculosis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Vestibular neuronitis			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Viral infection			
subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	0 / 42237 (0.00%)	1 / 42255 (0.00%)	0 / 1006 (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
Hypoglycaemia			

subjects affected / exposed	1 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (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

Serious adverse events	Placebo Immunogenicity Subset		
Total subjects affected by serious adverse events			
subjects affected / exposed	48 / 1005 (4.78%)		
number of deaths (all causes)	73		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	2 / 1005 (0.20%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer metastatic			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder adenocarcinoma stage unspecified				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clear cell renal cell carcinoma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colorectal cancer metastatic				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glioblastoma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glioma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic adenoma				

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypopharyngeal cancer				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal cancer				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukaemia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma metastatic				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of renal pelvis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melanoma recurrent				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesothelioma				

subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastasis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic gastric cancer				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic renal cell carcinoma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelodysplastic syndrome				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm prostate				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal adenocarcinoma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal carcinoma recurrent				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer metastatic				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer recurrent			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsil cancer			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct adenocarcinoma			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon neoplasm				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial cancer				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cancer recurrent				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Circulatory collapse				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic aneurysm				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic aneurysm rupture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				

subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intermittent claudication				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Temporal arteritis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant hypertension				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental death			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hernia obstructive			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical device complication				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden cardiac death				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Implant site fibrosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic reaction				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic shock				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Corneal graft rejection				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				

Benign prostatic hyperplasia				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Female genital tract fistula				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal prolapse				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acquired phimosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea exertional				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Sleep apnoea syndrome			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alveolitis allergic			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrothorax			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infiltration			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asphyxia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			

Bipolar disorder				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychotic disorder				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suicidal ideation				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Weight decreased				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Femur fracture				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Humerus fracture			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain contusion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	2 / 1005 (0.20%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fracture			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia postoperative			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac valve replacement complication			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Forearm fracture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foreign body aspiration				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incisional hernia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Kidney contusion				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament injury				

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes postoperative				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple injuries				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periprosthetic fracture				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post laminectomy syndrome				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural intestinal perforation				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendon injury				

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thermal burn				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention postoperative				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular graft occlusion				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural haemorrhage				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Angina pectoris				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				

subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac failure				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute coronary syndrome				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac asthma				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Sick sinus syndrome				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial tachycardia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery dissection			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Silent myocardial infarction			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebrovascular accident				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cerebral infarction				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient global amnesia				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peroneal nerve palsy			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radicular pain			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiculitis lumbosacral			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trigeminal neuralgia			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic encephalopathy				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral nerve lesion				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Idiopathic thrombocytopenic purpura				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal artery occlusion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macular fibrosis			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Ileus			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Rectal haemorrhage				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal perforation				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric perforation				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varices oesophageal				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal hernia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal haemorrhagic				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal stenosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin ulcer				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Calculus bladder				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis noninfective				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				

subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal impairment				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureteric stenosis				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral stenosis				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Finger deformity				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				

subjects affected / exposed	10 / 1005 (1.00%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone cyst			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polymyalgia rheumatica			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia legionella			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis suppurative			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal abscess			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	13vPnC Safety Set	Placebo Safety Set	13vPnC Immunogenicity Subset
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	363 / 1006 (36.08%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Keratoacanthoma			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Peripheral coldness			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Injection site erythema			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	30 / 1006 (2.98%)
occurrences (all)	0	0	30
Injection site pain			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	18 / 1006 (1.79%)
occurrences (all)	0	0	18
Injection site pruritus			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	10 / 1006 (0.99%)
occurrences (all)	0	0	10
Injection site swelling			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	10 / 1006 (0.99%)
occurrences (all)	0	0	10
Malaise			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	4 / 1006 (0.40%)
occurrences (all)	0	0	4
Fatigue			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Injection site haematoma			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Injection site exfoliation			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Cyst			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Device breakage			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Ill-defined disorder			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Vaccination site erythema			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Vessel puncture site haematoma			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Aggravated generalized joint pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	20 / 883 (2.27%)
occurrences (all)	0	0	20
Aggravated generalized joint pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	28 / 884 (3.17%)
occurrences (all)	0	0	28
Aggravated generalized joint pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[3]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 882 (0.34%)
occurrences (all)	0	0	3
Aggravated generalized muscle pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	41 / 886 (4.63%)
occurrences (all)	0	0	41
Aggravated generalized muscle pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	45 / 885 (5.08%)
occurrences (all)	0	0	45
Aggravated generalized muscle pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	6 / 882 (0.68%)
occurrences (all)	0	0	6
Decreased appetite (Systematic Event)	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	47 / 886 (5.30%)
occurrences (all)	0	0	47
Diarrhea: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	45 / 887 (5.07%)
occurrences (all)	0	0	45
Diarrhea: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[9]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	11 / 882 (1.25%)
occurrences (all)	0	0	11
Diarrhea: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	6 / 881 (0.68%)
occurrences (all)	0	0	6
Fatigue: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	123 / 892 (13.79%)
occurrences (all)	0	0	123
Fatigue: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	69 / 886 (7.79%)
occurrences (all)	0	0	69
Fatigue: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[13]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	12 / 883 (1.36%)
occurrences (all)	0	0	12
Fever: >=38.0 to <38.5 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	10 / 883 (1.13%)
occurrences (all)	0	0	10
Fever: >=38.5 to <39.0 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[15]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 881 (0.57%)
occurrences (all)	0	0	5
Fever: >=39.0 to <40.0 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	6 / 882 (0.68%)
occurrences (all)	0	0	6
Fever: >40 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	7 / 882 (0.79%)
occurrences (all)	0	0	7
Headache: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	116 / 891 (13.02%)
occurrences (all)	0	0	116
Headache: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[19]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	46 / 883 (5.21%)
occurrences (all)	0	0	46
Headache: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 881 (0.57%)
occurrences (all)	0	0	5
New generalized joint pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[21]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	44 / 884 (4.98%)
occurrences (all)	0	0	44
New generalized joint pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[22]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	26 / 883 (2.94%)
occurrences (all)	0	0	26
New generalized joint pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[23]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 882 (0.34%)
occurrences (all)	0	0	3
New generalized muscle pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[24]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	130 / 894 (14.54%)
occurrences (all)	0	0	130
New generalized muscle pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[25]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	52 / 886 (5.87%)
occurrences (all)	0	0	52
New generalized muscle pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[26]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	6 / 882 (0.68%)
occurrences (all)	0	0	6
Rash (Systematic Event)	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			

subjects affected / exposed[27]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	29 / 882 (3.29%)
occurrences (all)	0	0	29
Vomiting: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[28]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 881 (0.00%)
occurrences (all)	0	0	0
Vomiting: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[29]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 881 (0.11%)
occurrences (all)	0	0	1
Vomiting: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[30]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 881 (0.23%)
occurrences (all)	0	0	2
Chills (Systematic Event)	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic			
subjects affected / exposed[31]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	84 / 891 (9.43%)
occurrences (all)	0	0	84
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 1006 (0.50%)
occurrences (all)	0	0	5
Cough			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Hyperventilation			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Lung disorder			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 1006 (0.30%)
occurrences (all)	0	0	3
Rhinalgia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Investigations			
International normalised ratio decreased			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Contusion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Procedural pain			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Epicondylitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Periorbital contusion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Traumatic haemorrhage			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0

Palpitations			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	7 / 1006 (0.70%)
occurrences (all)	0	0	7
Dizziness			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 1006 (0.30%)
occurrences (all)	0	0	3
Ageusia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Aphonia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Transient ischaemic attack			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 1006 (0.50%)
occurrences (all)	0	0	5
Cataract			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 1006 (0.30%)
occurrences (all)	0	0	3
Nausea			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Change of bowel habit			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Blood blister			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Skin ulcer			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Limitation of arm movement: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	126 / 891 (14.14%)
occurrences (all)	0	0	126
Limitation of arm movement: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	110 / 888 (12.39%)
occurrences (all)	0	0	110
Limitation of arm movement: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[34]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	15 / 883 (1.70%)
occurrences (all)	0	0	15
Limitation of arm movement: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[35]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	11 / 882 (1.25%)
occurrences (all)	0	0	11
Pain: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is		

	same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[36]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	330 / 914 (36.11%)
occurrences (all)	0	0	330
Pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[37]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	300 / 913 (32.86%)
occurrences (all)	0	0	300
Pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[38]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	68 / 886 (7.67%)
occurrences (all)	0	0	68
Pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[39]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 881 (0.34%)
occurrences (all)	0	0	3
Redness: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[40]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	43 / 886 (4.85%)
occurrences (all)	0	0	43
Redness: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[41]	0 / 42237 (0.00%)	0 / 42255 (0.00%)	33 / 886 (3.72%)
occurrences (all)	0	0	33
Redness: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is		

	same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	0 / 42237 (0.00%) 0	0 / 42255 (0.00%) 0	15 / 881 (1.70%) 15
Redness: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[43] occurrences (all)	0 / 42237 (0.00%) 0	0 / 42255 (0.00%) 0	4 / 881 (0.45%) 4
Swelling: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[44] occurrences (all)	0 / 42237 (0.00%) 0	0 / 42255 (0.00%) 0	60 / 888 (6.76%) 60
Swelling: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[45] occurrences (all)	0 / 42237 (0.00%) 0	0 / 42255 (0.00%) 0	49 / 888 (5.52%) 49
Swelling: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[46] occurrences (all)	0 / 42237 (0.00%) 0	0 / 42255 (0.00%) 0	23 / 884 (2.60%) 23
Swelling: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[47] occurrences (all)	0 / 42237 (0.00%) 0	0 / 42255 (0.00%) 0	1 / 881 (0.11%) 1
Renal and urinary disorders			

Nephrolithiasis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 1006 (0.50%)
occurrences (all)	0	0	5
Tendonitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 1006 (0.30%)
occurrences (all)	0	0	3
Intervertebral disc protrusion			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	4 / 1006 (0.40%)
occurrences (all)	0	0	4
Arthralgia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	3 / 1006 (0.30%)
occurrences (all)	0	0	3
Fibromyalgia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			

subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Inclusion body myositis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Musculoskeletal discomfort			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Musculoskeletal disorder			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Osteitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	12 / 1006 (1.19%)
occurrences (all)	0	0	12
Upper respiratory tract infection			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	8 / 1006 (0.80%)
occurrences (all)	0	0	8
Cystitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 1006 (0.50%)
occurrences (all)	0	0	5
Gastroenteritis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	4 / 1006 (0.40%)
occurrences (all)	0	0	4
Bronchitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	5 / 1006 (0.50%)
occurrences (all)	0	0	5
Influenza			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	4 / 1006 (0.40%)
occurrences (all)	0	0	4
Herpes zoster			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Fungal infection			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	2 / 1006 (0.20%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0

Abscess oral			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Tinea barbae			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	0 / 1006 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 42237 (0.00%)	0 / 42255 (0.00%)	1 / 1006 (0.10%)
occurrences (all)	0	0	1

Non-serious adverse events	Placebo Immunogenicity Subset		

Total subjects affected by non-serious adverse events subjects affected / exposed	315 / 1005 (31.34%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Keratoacanthoma subjects affected / exposed occurrences (all)	 0 / 1005 (0.00%) 0		
Vascular disorders Hypertension subjects affected / exposed occurrences (all) Peripheral coldness subjects affected / exposed occurrences (all)	 0 / 1005 (0.00%) 0 1 / 1005 (0.10%) 1		
General disorders and administration site conditions Injection site erythema subjects affected / exposed occurrences (all) Injection site pain subjects affected / exposed occurrences (all) Injection site pruritus subjects affected / exposed occurrences (all) Injection site swelling subjects affected / exposed occurrences (all) Malaise subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Injection site haematoma subjects affected / exposed occurrences (all) Injection site exfoliation	 0 / 1005 (0.00%) 0 2 / 1005 (0.20%) 2 0 / 1005 (0.00%) 0 0 / 1005 (0.00%) 0 3 / 1005 (0.30%) 3 4 / 1005 (0.40%) 4 2 / 1005 (0.20%) 2		

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Cyst			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Device breakage			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Ill-defined disorder			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Injection site rash			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Vaccination site erythema			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Vessel puncture site haematoma			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Aggravated generalized joint pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[1]	15 / 861 (1.74%)		
occurrences (all)	15		
Aggravated generalized joint pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	22 / 862 (2.55%)		
occurrences (all)	22		
Aggravated generalized joint pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	3 / 860 (0.35%)		
occurrences (all)	3		
Aggravated generalized muscle pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	16 / 862 (1.86%)		
occurrences (all)	16		
Aggravated generalized muscle pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	24 / 863 (2.78%)		
occurrences (all)	24		
Aggravated generalized muscle pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	1 / 860 (0.12%)		
occurrences (all)	1		
Decreased appetite (Systematic Event)	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[7]	32 / 865 (3.70%)		
occurrences (all)	32		
Diarrhea: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[8]	67 / 868 (7.72%)		
occurrences (all)	67		
Diarrhea: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[9]	9 / 863 (1.04%)		
occurrences (all)	9		
Diarrhea: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[10]	4 / 862 (0.46%)		
occurrences (all)	4		
Fatigue: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[11]	102 / 871 (11.71%)		
occurrences (all)	102		
Fatigue: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[12]	54 / 866 (6.24%)		
occurrences (all)	54		
Fatigue: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[13]	8 / 863 (0.93%)		
occurrences (all)	8		
Fever: >=38.0 to <38.5 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[14]	5 / 859 (0.58%)		
occurrences (all)	5		
Fever: >=38.5 to <39.0 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[15]	2 / 859 (0.23%)		
occurrences (all)	2		
Fever: >=39.0 to <40.0 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[16]	2 / 859 (0.23%)		
occurrences (all)	2		
Fever: >40 degrees C	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[17]	3 / 860 (0.35%)		
occurrences (all)	3		
Headache: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[18]	114 / 870 (13.10%)		
occurrences (all)	114		
Headache: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[19]	33 / 868 (3.80%)		
occurrences (all)	33		
Headache: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[20]	5 / 861 (0.58%)		
occurrences (all)	5		
New generalized joint pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[21]	34 / 862 (3.94%)		
occurrences (all)	34		
New generalized joint pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[22]	19 / 864 (2.20%)		
occurrences (all)	19		
New generalized joint pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[23]	3 / 860 (0.35%)		
occurrences (all)	3		
New generalized muscle pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[24]	58 / 865 (6.71%)		
occurrences (all)	58		
New generalized muscle pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[25]	24 / 863 (2.78%)		
occurrences (all)	24		
New generalized muscle pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[26]	4 / 860 (0.47%)		
occurrences (all)	4		
Rash (Systematic Event)	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[27]	7 / 860 (0.81%)		
occurrences (all)	7		
Vomiting: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[28]	6 / 860 (0.70%)		
occurrences (all)	6		
Vomiting: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[29]	1 / 860 (0.12%)		
occurrences (all)	1		
Vomiting: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[30]	1 / 860 (0.12%)		
occurrences (all)	1		
Chills (Systematic Event)	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Systemic Events 0.0			
alternative assessment type: Systematic			

subjects affected / exposed[31]	73 / 866 (8.43%)		
occurrences (all)	73		
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	2 / 1005 (0.20%)		
occurrences (all)	2		
Cough			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Hyperventilation			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Lung disorder			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Rhinalgia			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Sneezing			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Investigations			

International normalised ratio decreased			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	2		
Procedural pain			
subjects affected / exposed	2 / 1005 (0.20%)		
occurrences (all)	2		
Bone contusion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Concussion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Epicondylitis			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Face injury			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Muscle strain			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Periorbital contusion			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Traumatic haemorrhage			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Cardiac disorders			

Angina pectoris subjects affected / exposed occurrences (all)	2 / 1005 (0.20%) 2			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0			
Cardiac failure subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1			
Mitral valve incompetence subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1			
Palpitations subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0			
Tachycardia subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0			
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1			
Dizziness subjects affected / exposed occurrences (all)	3 / 1005 (0.30%) 3			
Ageusia subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1			
Aphonia subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1			
Cerebrovascular accident subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1			
Neuropathy peripheral				

subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Paraesthesia subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Sciatica subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Syncope subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Transient ischaemic attack subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Cataract subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Vitreous floaters subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Gastrointestinal disorders			

Diarrhoea subjects affected / exposed occurrences (all)	5 / 1005 (0.50%) 5		
Nausea subjects affected / exposed occurrences (all)	3 / 1005 (0.30%) 3		
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	2 / 1005 (0.20%) 2		
Change of bowel habit subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Eructation subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Gastritis subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Haemorrhoids subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Vomiting subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Hepatobiliary disorders Cholelithiasis subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Skin and subcutaneous tissue disorders Blood blister subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Dermatitis allergic			

subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Pruritus generalised			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Skin ulcer			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Limitation of arm movement: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[32]	28 / 865 (3.24%)		
occurrences (all)	28		
Limitation of arm movement: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0			
alternative assessment type: Systematic			
subjects affected / exposed[33]	22 / 863 (2.55%)		
occurrences (all)	22		
Limitation of arm movement:	Additional description: Subjects affected and Occurrences for LRs and SEs is		

Moderate	same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[34] occurrences (all)	4 / 860 (0.47%) 4		
Limitation of arm movement: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[35] occurrences (all)	6 / 861 (0.70%) 6		
Pain: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[36] occurrences (all)	53 / 863 (6.14%) 53		
Pain: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[37] occurrences (all)	48 / 861 (5.57%) 48		
Pain: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[38] occurrences (all)	5 / 860 (0.58%) 5		
Pain: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[39] occurrences (all)	1 / 860 (0.12%) 1		
Redness: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is		

	same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[40] occurrences (all)	10 / 859 (1.16%) 10		
Redness: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[41] occurrences (all)	7 / 859 (0.81%) 7		
Redness: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[42] occurrences (all)	3 / 859 (0.35%) 3		
Redness: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[43] occurrences (all)	1 / 859 (0.12%) 1		
Swelling: Any	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[44] occurrences (all)	10 / 859 (1.16%) 10		
Swelling: Mild	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[45] occurrences (all)	6 / 859 (0.70%) 6		
Swelling: Moderate	Additional description: Subjects affected and Occurrences for LRs and SEs is		

	same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[46] occurrences (all)	5 / 859 (0.58%) 5		
Swelling: Severe	Additional description: Subjects affected and Occurrences for LRs and SEs is same as ediaries could not distinguish 1 occurrence from another within a subject/vaccination.		
alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed[47] occurrences (all)	1 / 859 (0.12%) 1		
Renal and urinary disorders			
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Haematuria subjects affected / exposed occurrences (all)	0 / 1005 (0.00%) 0		
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Tendonitis subjects affected / exposed occurrences (all)	2 / 1005 (0.20%) 2		
Myalgia subjects affected / exposed occurrences (all)	3 / 1005 (0.30%) 3		
Intervertebral disc protrusion subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Musculoskeletal stiffness			

subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Arthralgia				
subjects affected / exposed	3 / 1005 (0.30%)			
occurrences (all)	3			
Pain in extremity				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Fibromyalgia				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Joint range of motion decreased				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Joint stiffness				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Inclusion body myositis				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Muscle spasms				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Muscular weakness				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Musculoskeletal discomfort				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Musculoskeletal disorder				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Musculoskeletal pain				

subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Myositis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Osteitis			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Pain in jaw			
subjects affected / exposed	0 / 1005 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	20 / 1005 (1.99%)		
occurrences (all)	20		
Upper respiratory tract infection			
subjects affected / exposed	17 / 1005 (1.69%)		
occurrences (all)	17		
Cystitis			
subjects affected / exposed	8 / 1005 (0.80%)		
occurrences (all)	8		
Gastroenteritis			
subjects affected / exposed	9 / 1005 (0.90%)		
occurrences (all)	9		
Bronchitis			
subjects affected / exposed	4 / 1005 (0.40%)		
occurrences (all)	4		
Influenza			
subjects affected / exposed	5 / 1005 (0.50%)		
occurrences (all)	5		
Herpes zoster			
subjects affected / exposed	1 / 1005 (0.10%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	3 / 1005 (0.30%)		
occurrences (all)	3		

Sinusitis				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Fungal infection				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Wound infection				
subjects affected / exposed	2 / 1005 (0.20%)			
occurrences (all)	2			
Abscess oral				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Enteritis infectious				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Fungal skin infection				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Oral herpes				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	1 / 1005 (0.10%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	0 / 1005 (0.00%)			
occurrences (all)	0			

Tinea barbae subjects affected / exposed occurrences (all)	1 / 1005 (0.10%) 1		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) Gout subjects affected / exposed occurrences (all)	 3 / 1005 (0.30%) 3 2 / 1005 (0.20%) 2		

Notes:

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

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

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 August 2008	Addition of recording of newly diagnosed chronic medical conditions, analysis of death data for safety, subgroup analyses for local reactions, systemic events, adverse events, and immunogenicity.
28 May 2010	Change in start of SAE reporting period for vaccination of subjects in the placebo group with 13vPnC from vaccine administration to signing of ICD, deletion of subgroup analysis of safety data for age strata.
10 May 2011	Reduction in frequency of data collection regarding death and loss to follow-up.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported