



## Clinical trial results: Efficacy, Immunogenicity, and Safety Study of Clostridium difficile Toxoid Vaccine in Subjects at Risk for C. difficile Infection

### Summary

EudraCT number	2013-000775-32
Trial protocol	FI SE GB DE ES DK PL CZ RO
Global end of trial date	12 June 2018

### Results information

Result version number	v2 (current)
This version publication date	20 January 2023
First version publication date	27 June 2019
Version creation reason	<ul style="list-style-type: none"><li>• Correction of full data set</li><li>Updated safety optional field</li></ul>

### Trial information

#### Trial identification

Sponsor protocol code	H-030-014
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01887912
WHO universal trial number (UTN)	U1111-1127-7162

Notes:

### Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	1 Discovery Drive, Swiftwater, PA, United States, 18370
Public contact	Sanofi Pasteur, Trial Transparency Team, Contact-US@sanofi.com
Scientific contact	Sanofi Pasteur, Trial Transparency Team, Contact-US@sanofi.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	11 January 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 June 2018
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

To assess the efficacy of the C. difficile vaccine in preventing the onset of symptomatic primary C. difficile infection (CDI) confirmed by polymerase chain reaction (PCR) in adult subjects aged  $\geq 50$  years who are at risk for CDI and have received at least 1 injection

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 July 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 58
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	Spain: 145
Country: Number of subjects enrolled	Sweden: 11
Country: Number of subjects enrolled	United Kingdom: 207
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Finland: 343
Country: Number of subjects enrolled	France: 210
Country: Number of subjects enrolled	Germany: 198
Country: Number of subjects enrolled	Australia: 170
Country: Number of subjects enrolled	Japan: 194
Country: Number of subjects enrolled	Korea, Republic of: 428
Country: Number of subjects enrolled	Philippines: 233
Country: Number of subjects enrolled	Singapore: 161
Country: Number of subjects enrolled	Taiwan: 127
Country: Number of subjects enrolled	Thailand: 24
Country: Number of subjects enrolled	Brazil: 1151
Country: Number of subjects enrolled	Chile: 7
Country: Number of subjects enrolled	Colombia: 974

Country: Number of subjects enrolled	Costa Rica: 11
Country: Number of subjects enrolled	Dominica: 54
Country: Number of subjects enrolled	Guatemala: 2
Country: Number of subjects enrolled	Mexico: 577
Country: Number of subjects enrolled	Panama: 39
Country: Number of subjects enrolled	Peru: 464
Country: Number of subjects enrolled	Canada: 327
Country: Number of subjects enrolled	Puerto Rico: 17
Country: Number of subjects enrolled	United States: 3159
Worldwide total number of subjects	9302
EEA total number of subjects	1183

Notes:

<b>Subjects enrolled per age group</b>	
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)	4414
From 65 to 84 years	4716
85 years and over	172

## Subject disposition

### Recruitment

Recruitment details:

Study subjects were enrolled in the study from 30 July 2013 to 17 November 2017.

### Pre-assignment

Screening details:

A total of 9302 subjects were enrolled and randomized in the study.

### 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, Assessor

Blinding implementation details:

This study was observer-blind. The vaccine preparer and administrator may have been unblinded to treatment assignment due to the steps necessary for vaccine preparation. However, the subject, the Investigator, and study staff members who collected the safety data and laboratory personnel who analysed the blood and stool samples were all blinded to the group.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	C. Difficile Vaccine Group

Arm description:

Subjects received 1 injection of 0.5 milliliter (mL) C. difficile toxoid vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).

Arm type	Experimental
Investigational medicinal product name	C. difficile Toxoid Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 injection of 0.5 mL C. difficile toxoid vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).

<b>Arm title</b>	Placebo Group
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Arm description:

Subjects received 1 injection of 0.5 mL placebo matched to vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).

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

Dosage and administration details:

1 injection of 0.5 mL placebo matched to vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).

<b>Number of subjects in period 1</b>	<b>C. Difficile Vaccine Group</b>	<b>Placebo Group</b>
Started	6201	3101
Safety Population	6113	3057
Completed	4809	2370
Not completed	1392	731
Consent withdrawn by subject	606	349
Adverse event	34	15
Unspecified	122	58
Serious adverse event	400	198
Lost to follow-up	163	74
Protocol deviation	67	37

## Baseline characteristics

### Reporting groups

Reporting group title	C. Difficile Vaccine Group
Reporting group description: Subjects received 1 injection of 0.5 milliliter (mL) C. difficile toxoid vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).	
Reporting group title	Placebo Group
Reporting group description: Subjects received 1 injection of 0.5 mL placebo matched to vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).	

Reporting group values	C. Difficile Vaccine Group	Placebo Group	Total
Number of subjects	6201	3101	9302
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	65.9 ± 8.86	65.8 ± 8.87	-
Gender categorical Units: Subjects			
Female	2629	1294	3923
Male	3572	1807	5379
Ethnicity Units: Subjects			
Hispanic or Latino	330	171	501
Not Hispanic or Latino	2780	1390	4170
Unknown or Not Reported	3091	1540	4631
Race Units: Subjects			
American Indian or Alaska Native	6	6	12
Asian	795	398	1193
Native Hawaiian or Other Pacific Islander	5	4	9
Black or African American	206	102	308
White	2983	1487	4470
More than one race	8	5	13
Unknown or Not Reported	2198	1099	3297

## End points

### End points reporting groups

Reporting group title	C. Difficile Vaccine Group
Reporting group description:	
Subjects received 1 injection of 0.5 milliliter (mL) C. difficile toxoid vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).	
Reporting group title	Placebo Group
Reporting group description:	
Subjects received 1 injection of 0.5 mL placebo matched to vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).	

### Primary: Number of Subjects With Symptomatic PCR-Confirmed Primary CDI Cases

End point title	Number of Subjects With Symptomatic PCR-Confirmed Primary CDI Cases <sup>[1]</sup>
End point description:	
Symptomatic PCR-confirmed CDI cases were defined as the number of subjects with combination of clinical and laboratory findings. Clinical components were: $\geq 3$ loose stools in $\leq 24$ hours, loose stools (defined as type 6 [fluffy pieces with ragged edges, mushy] or type 7 [watery, no solid pieces] according to the Bristol Stool Chart) lasting $\geq 24$ hours. Laboratory findings were: stool sample positive for C. difficile Toxin B by PCR at central laboratory or diagnosis of pseudomembranous colitis visualized at colonoscopy. Analysis was performed on modified intent-to-treat (mITT) population which included all subjects who received at least 1 injection and were analyzed according to the group to which they were randomized.	
End point type	Primary
End point timeframe:	
Up to 3 years post injection 1	

Notes:

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

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

End point values	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6173	3085		
Units: subjects	34	16		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects With Severe PCR-Confirmed Primary CDI Cases

End point title	Number of Subjects With Severe PCR-Confirmed Primary CDI Cases
End point description:	
Severe CDI cases were defined as number of subjects with at least one of the following symptoms: fever $\geq 38.5$ degree Celsius ( $^{\circ}\text{C}$ ), white blood cell count $\geq 15,000$ cells/ $\text{mm}^3$ , ileus, pseudomembranous colitis, serum albumin $<3$ gram per deciliter, abdominal distension, abdominal tenderness, or admission to the intensive care unit within 7 days of CDI diagnosis. Analysis was performed on subjects with protocol-defined (PCR confirmed) primary CDI cases.	

End point type	Secondary
End point timeframe:	
Up to 3 years post injection 1	

End point values	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	16		
Units: subjects	9	6		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects With Loose Stool Episodes

End point title	Number of Subjects With Loose Stool Episodes			
End point description:				
Loose stools were defined as type 6 (fluffy pieces with ragged edges, mushy) or type 7 (watery, no solid pieces) according to the Bristol Stool Chart. In this endpoint, subject with number of loose stool episodes (categorized as: loose stool episodes less than 3, 3 to 6, 7 to 10, 11 to 15 and greater than 15) were reported. Analysis was performed on subjects with protocol-defined (PCR confirmed) primary CDI cases.				
End point type	Secondary			
End point timeframe:				
Up to 3 years post injection 1				

End point values	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	16		
Units: subjects				
<3	0	0		
3 to 6	7	4		
7 to 10	7	2		
11 to 15	7	4		
>15	13	6		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects With Symptomatic PCR Confirmed CDI Cases: Per-Protocol Population

End point title	Number of Subjects With Symptomatic PCR Confirmed CDI Cases: Per-Protocol Population
End point description:	
Symptomatic PCR confirmed CDI cases were defined as the number of subjects with combination of clinical and laboratory findings. Clinical components were: $\geq 3$ loose stools in $\leq 24$ hours, loose stools (defined as type 6 [fluffy pieces with ragged edges, mushy] or type 7 [watery, no solid pieces] according to the Bristol Stool Chart) lasting $\geq 24$ hours. Laboratory findings were: stool sample positive for C. difficile Toxin B by PCR at central laboratory or diagnosis of pseudomembranous colitis visualized at colonoscopy. Analysis was performed on per-protocol efficacy analysis set (PPEAS) which included subjects who had at least 1 injection, no relevant protocol deviations (not meet inclusion criteria/ met exclusion criteria, not receive any vaccine/not received in proper time window, received different vaccine than randomized, preparation and / or administration of vaccine not done per protocol, received protocol-restricted therapy).	
End point type	Secondary
End point timeframe:	
Up to 3 years post injection 1	

End point values	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4786	2378		
Units: subjects	23	13		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum Antibody Concentrations Against Toxins A and B Measured by Enzyme-linked Immunosorbent Assay (ELISA)

End point title	Serum Antibody Concentrations Against Toxins A and B Measured by Enzyme-linked Immunosorbent Assay (ELISA)
End point description:	
Serum antibody concentrations against toxins A and B were measured by ELISA and expressed as geometric mean concentration (GMC). The 2-sided 95% Confidence Interval (CI) of GMC was based on the Student t-distribution. Analysis was performed on Per Protocol Immunogenicity Analysis Set, which included subjects who had at least 1 injection, no relevant protocol deviations (not met inclusion criteria/ met exclusion criteria, not received vaccine/ not received in proper time window, received different vaccine than randomized, preparation and/ or administration of vaccine not per protocol, protocol-restricted therapy, not provided post-dose serology sample/serology sample did not produced a valid test result). Here, 'n' = subjects with available data for each specified category for each arm respectively.	
End point type	Secondary
End point timeframe:	
Day 0, Day 14, Day 30, Day 60, Day 210, Day 390, Day 570, Day 750, Day 930, and Day 1110	

<b>End point values</b>	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	471	236		
Units: ELISA units per milliliter (EU/mL)				
geometric mean (confidence interval 95%)				
Toxin A ImmunoglobulinG (IgG): Day 0 (n=468, 230)	0.957 (0.897 to 1.02)	0.999 (0.912 to 1.09)		
Toxin A IgG: Day 14 (n=418, 214)	3.19 (2.68 to 3.80)	0.913 (0.849 to 0.983)		
Toxin A IgG: Day 30 (n=456, 230)	12.2 (10.4 to 14.3)	0.959 (0.889 to 1.03)		
Toxin A IgG: Day 60 (n=417, 212)	43.7 (38.1 to 50.2)	0.933 (0.867 to 1.00)		
Toxin A IgG: Day 210 (n=355, 182)	12.0 (10.5 to 13.8)	0.944 (0.865 to 1.03)		
Toxin A IgG: Day 390 (n=320, 159)	6.02 (5.23 to 6.93)	0.955 (0.856 to 1.06)		
Toxin A IgG: Day 570 (n=277, 145)	4.50 (3.86 to 5.25)	0.908 (0.834 to 0.989)		
Toxin A IgG: Day 750 (n=191, 93)	4.02 (3.38 to 4.78)	0.856 (0.776 to 0.944)		
Toxin A IgG: Day 930 (n=108, 66)	3.83 (3.02 to 4.85)	0.902 (0.796 to 1.02)		
Toxin A IgG: Day 1110 (n=59, 36)	3.75 (2.64 to 5.34)	1.09 (0.786 to 1.50)		
Toxin B IgG: Day 0 (n=468, 231)	1.40 (1.24 to 1.57)	1.49 (1.24 to 1.79)		
Toxin B IgG: Day 14 (n=419, 216)	4.36 (3.37 to 5.64)	1.56 (1.29 to 1.89)		
Toxin B IgG: Day 30 (n=455, 231)	10.0 (7.85 to 12.8)	1.46 (1.21 to 1.75)		
Toxin B IgG: Day 60 (n=417, 212)	24.8 (20.1 to 30.6)	1.42 (1.18 to 1.71)		
Toxin B IgG: Day 210 (n=354, 182)	6.62 (5.36 to 8.19)	1.31 (1.07 to 1.61)		
Toxin B IgG: Day 390 (n=319, 159)	3.98 (3.15 to 5.02)	1.24 (0.991 to 1.56)		
Toxin B IgG: Day 570 (n=277, 145)	3.37 (2.63 to 4.32)	1.15 (0.905 to 1.47)		
Toxin B IgG: Day 750 (n=191, 93)	2.86 (2.14 to 3.84)	1.11 (0.840 to 1.47)		
Toxin B IgG: Day 930 (n=108, 66)	2.42 (1.65 to 3.55)	1.13 (0.812 to 1.58)		
Toxin B IgG: Day 1110 (n=59, 36)	3.46 (2.06 to 5.81)	0.966 (0.592 to 1.58)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects With $\geq 2$ and 4-Fold Rise in Serum Antibody Concentrations From Baseline Against Toxins A and B Measured by ELISA

End point title	Percentage of Subjects With $\geq 2$ and 4-Fold Rise in Serum Antibody Concentrations From Baseline Against Toxins A and B Measured by ELISA
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End point description:

Percentage of subjects with  $\geq 2$  and 4-fold rise in serum antibody concentrations against toxins A and B were measured by ELISA. The 2-sided 95% CI of the percentage was based on Exact method calculations. Analysis was performed on Per Protocol Immunogenicity Analysis Set. Here, 'number of subjects analysed' = subjects evaluable for this outcome measure and 'n' = subjects with available data for each specified category for each arm respectively.

End point type Secondary

End point timeframe:

Day 60

End point values	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	220		
Units: percentage of subjects				
number (confidence interval 95%)				
Toxin A IgG: $\geq 2$ (n=433, 217)	93.3 (90.5 to 95.5)	0.9 (0.1 to 3.3)		
Toxin A IgG: $\geq 4$ (n=433, 217)	88.9 (85.6 to 91.7)	0.0 (0.0 to 1.7)		
Toxin B IgG: $\geq 2$ (n=433, 218)	82.2 (78.3 to 85.7)	4.6 (2.2 to 8.3)		
Toxin B IgG: $\geq 4$ (n=433, 218)	73.2 (68.8 to 77.3)	0.5 (0.0 to 2.5)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum Antibody Concentrations Against Toxins A and B Measured by ELISA in Subjects With CDI

End point title Serum Antibody Concentrations Against Toxins A and B Measured by ELISA in Subjects With CDI

End point description:

Serum antibody concentrations against toxins A and B were measured by ELISA and expressed as GMC. The 2-sided 95% CI GMC was based on the Student t-distribution. Symptomatic PCR-confirmed CDI cases were defined as the number of subjects with combination of clinical and laboratory findings. Clinical components were:  $\geq 3$  loose stools in  $\leq 24$  hours, loose stools (defined as type 6 [fluffy pieces with ragged edges, mushy] or type 7 [watery, no solid pieces] according to the Bristol Stool Chart) lasting  $\geq 24$  hours. Laboratory findings were: stool sample positive for C. difficile Toxin B by PCR at central laboratory or diagnosis of pseudomembranous colitis visualized at colonoscopy. Analysis was performed on subjects with protocol-defined (PCR confirmed) primary CDI cases. Here, 'n' = subjects with available data for each specified category.

End point type Secondary

End point timeframe:

Day 0 and Day 60

<b>End point values</b>	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	16		
Units: EU/mL				
geometric mean (confidence interval 95%)				
Toxin A IgG: Day 0 (n=33, 16)	1.15 (0.821 to 1.62)	1.04 (0.661 to 1.64)		
Toxin A IgG: Day 60 (n=30, 16)	42.1 (18.0 to 98.3)	1.06 (0.632 to 1.76)		
Toxin B IgG: Day 0 (n=33, 16)	1.41 (0.762 to 2.62)	1.05 (0.504 to 2.20)		
Toxin B IgG: Day 60 (n=30, 16)	19.3 (6.65 to 56.2)	1.13 (0.609 to 2.11)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Serum Antibody Concentrations Against Toxins A and B Measured by Toxin Neutralization Assay (TNA)

End point title	Serum Antibody Concentrations Against Toxins A and B Measured by Toxin Neutralization Assay (TNA)
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End point description:

Serum antibody concentrations against toxins A and B were measured by TNA and expressed as geometric mean titer (GMT). The 2-sided 95% CI of GMT was based on the Student t-distribution. Analysis was performed on Per Protocol Immunogenicity Analysis Set. Here, 'n' = subjects with available data for each specified category for each arm respectively.

End point type	Secondary
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End point timeframe:

Day 0, Day 14, Day 30, Day 60, Day 210, Day 390, Day 570, Day 750, Day 930, and Day 1110

<b>End point values</b>	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	471	236		
Units: Titer (1/dilution)				
geometric mean (confidence interval 95%)				
Toxin A TNA: Day 0 (n=466, 231)	9.86 (9.22 to 10.5)	10.1 (9.12 to 11.2)		
Toxin A TNA: Day 14 (n=419, 216)	28.5 (22.7 to 35.8)	9.86 (8.96 to 10.8)		
Toxin A TNA: Day 30 (n=456, 231)	50.5 (40.9 to 62.3)	9.97 (9.09 to 10.9)		
Toxin A TNA: Day 60 (n=416, 212)	269 (226 to 322)	9.82 (8.95 to 10.8)		
Toxin A TNA: Day 210 (n=354, 181)	269 (228 to 317)	10.3 (9.09 to 11.7)		
Toxin A TNA: Day 390 (n=320, 159)	217 (183 to 259)	10.1 (8.86 to 11.5)		

Toxin A TNA: Day 570 (n=277, 145)	184 (153 to 223)	9.86 (8.76 to 11.1)		
Toxin A TNA: Day 750 (n=191, 93)	186 (148 to 234)	10.2 (8.66 to 12.0)		
Toxin A TNA: Day 930 (n=108, 66)	173 (125 to 240)	10.7 (8.57 to 13.4)		
Toxin A TNA: Day 1110 (n=59, 36)	212 (137 to 329)	10.2 (8.03 to 12.9)		
Toxin B TNA: Day 0 (n=466, 230)	12.3 (11.2 to 13.6)	13.2 (11.2 to 15.6)		
Toxin B TNA: Day 14 (n=419, 216)	32.7 (25.3 to 42.2)	13.3 (11.3 to 15.7)		
Toxin B TNA: Day 30 (n=456, 231)	37.8 (29.3 to 48.8)	13.4 (11.3 to 15.8)		
Toxin B TNA: Day 60 (n=416, 212)	43.9 (34.0 to 56.6)	14.3 (11.9 to 17.2)		
Toxin B TNA: Day 210 (n=354, 181)	41.4 (32.4 to 53.1)	13.2 (11.1 to 15.5)		
Toxin B TNA: Day 390 (n=319, 159)	38.4 (30.0 to 49.0)	13.5 (11.3 to 16.1)		
Toxin B TNA: Day 570 (n=277, 145)	35.7 (27.7 to 46.0)	13.7 (11.3 to 16.8)		
Toxin B TNA: Day 750 (n=191, 93)	34.3 (25.1 to 46.9)	14.6 (11.2 to 18.9)		
Toxin B TNA: Day 930 (n=108, 66)	31.0 (21.1 to 45.6)	17.0 (12.3 to 23.5)		
Toxin B TNA: Day 1110 (n=59, 36)	46.8 (26.1 to 84.1)	14.0 (9.05 to 21.7)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects With $\geq 2$ and 4-Fold Rise in Serum Antibody Concentrations From Baseline Against Toxins A and B Measured by TNA

End point title	Percentage of Subjects With $\geq 2$ and 4-Fold Rise in Serum Antibody Concentrations From Baseline Against Toxins A and B Measured by TNA
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End point description:

Percentage of subjects with  $\geq 2$  and 4-fold rise in serum antibody concentrations against toxins A and B were measured by TNA. The 2-sided 95% CI of the percentage was based on Exact method calculations. Analysis was performed on Per Protocol Immunogenicity Analysis Set. Here, 'number of subjects analysed' = subjects evaluable for this outcome measure and 'n' = subjects with available data for each specified category for each arm respectively.

End point type	Secondary
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End point timeframe:

Day 60

<b>End point values</b>	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	220		
Units: percentage of subjects				
number (confidence interval 95%)				
Toxin A TNA: >=2 (n=431, 218)	85.6 (81.9 to 88.8)	0.5 (0.0 to 2.5)		
Toxin A TNA: >=4 (n=431, 218)	78.2 (74.0 to 82.0)	0.5 (0.0 to 2.5)		
Toxin B TNA: >=2 (n=431, 217)	30.9 (26.5 to 35.5)	2.8 (1.0 to 5.9)		
Toxin B TNA: >=4 (n=431, 217)	27.4 (23.2 to 31.8)	1.8 (0.5 to 4.7)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Serum Antibody Concentrations Against Toxins A and B Measured by TNA in Subjects With CDI

End point title	Serum Antibody Concentrations Against Toxins A and B Measured by TNA in Subjects With CDI
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End point description:

Serum antibody concentrations against toxins A and B were measured by TNA and were expressed as GMT. The 2-sided 95% CI GMC was based on the Student t-distribution. Symptomatic PCR confirmed CDI cases were defined as the number of subjects with combination of clinical and laboratory findings. Clinical components were: >= 3 loose stools in <= 24 hours, loose stools (defined as type 6 [fluffy pieces with ragged edges, mushy] or type 7 [watery, no solid pieces] according to the Bristol Stool Chart) lasting >= 24 hours. Laboratory findings were: stool sample positive for C. difficile Toxin B by PCR at central laboratory or diagnosis of pseudomembranous colitis visualized at colonoscopy. Analysis was performed on subjects with protocol-defined CDI cases. Here, 'n' = subjects with available data for each specified category for each arm respectively.

End point type	Secondary
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End point timeframe:

Day 0 and Day 60

<b>End point values</b>	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	16		
Units: Titer (1/dilution)				
geometric mean (confidence interval 95%)				
Toxin A TNA: Day 0 (n=33, 16)	12.4 (8.59 to 17.9)	12.0 (6.27 to 23.0)		
Toxin A TNA: Day 60 (n=30, 16)	176 (83.4 to 371)	10.7 (5.77 to 19.7)		
Toxin B TNA: Day 0 (n=33, 16)	16.7 (9.46 to 29.5)	11.1 (7.57 to 16.3)		
Toxin B TNA: Day 60 (n=30, 16)	53.0 (18.3 to 153)	13.1 (8.11 to 21.0)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Reporting Solicited Injection Site and Systemic Reactions

End point title	Percentage of Subjects Reporting Solicited Injection Site and Systemic Reactions
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End point description:

Solicited injection site reactions: Pain: Grade 1: no interference with activity, Grade 2: some interference with activity, Grade 3: significant; prevents daily activity; Erythema, swelling: Grade 1:  $\geq 25$  to  $\leq 50$  mm, Grade 2:  $> 51$  to  $\leq 100$  mm, Grade 3:  $> 100$  mm. Solicited systemic reactions: fever, headache, malaise, myalgia, arthralgia. Fever: Grade 1:  $\geq 38.0^{\circ}\text{C}$  to  $\leq 38.4^{\circ}\text{C}$  or  $\geq 100.4^{\circ}\text{F}$  to  $\leq 101.1^{\circ}\text{F}$ , Grade 2:  $\geq 38.5^{\circ}\text{C}$  to  $\leq 38.9^{\circ}\text{C}$  or  $\geq 101.2^{\circ}\text{F}$  to  $\leq 102.0^{\circ}\text{F}$ , Grade 3:  $\geq 39.0^{\circ}\text{C}$  or  $\geq 102.1^{\circ}\text{F}$ . Headache, malaise, and myalgia: Grade 1: no interference with activity, Grade 2: some interference with activity, Grade 3: significant; prevents daily activity; Arthralgia: Grade 1: free range of motion but complains of pain or discomfort, Grade 2: decreased range of motion due to pain or discomfort, Grade 3: unwilling to move due to pain. All subjects who received vaccine and were evaluable for reactogenicity. 'n'=subjects with available data for each category for each arm respectively.

End point type	Secondary
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End point timeframe:

Day 0 to Day 6 after any vaccination

End point values	C. Difficile Vaccine Group	Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1227	608		
Units: percentage of subjects				
number (not applicable)				
Injection site Pain (n=1199, 586)	38.6	13.5		
Injection site Erythema (n=1196, 587)	4.2	0.0		
Injection site Swelling (n=1197, 587)	3.8	0.3		
Fever (n=1173, 577)	4.8	5.7		
Headache (n=1196, 586)	25.3	22.5		
Malaise (n=1196, 586)	23.9	19.6		
Myalgia (n=1196, 586)	26.6	21.2		
Arthralgia (n=1196, 586)	19.5	16.7		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Unsolicited adverse event (AE) collected from Day 0 (post-vaccination) upto 30 days after last vaccination (upto 13 months). Solicited Reaction (SR): for 6 days following each vaccination. Serious adverse event (SAE): throughout the study (upto 3 years)

Adverse event reporting additional description:

Safety Analysis Set included all subjects who received at least 1 study or control vaccine and analysed according to vaccine received. SR: an AE prelisted (i.e., solicited) in electronic case report form (eCRF) and considered related to vaccination. An unsolicited AE was an observed AE that did not fulfill the prelisted conditions in eCRF.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

### Reporting groups

Reporting group title	C. Difficile Vaccine Group
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Reporting group description:

Subjects received 1 injection of 0.5 mL C. difficile toxoid vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).

Reporting group title	Placebo Group
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Reporting group description:

Subjects received 1 injection of 0.5 mL placebo matched to vaccine at Days 0 (Injection 1), 7 (Injection 2), and 30 (Injection 3).

Serious adverse events	C. Difficile Vaccine Group	Placebo Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1662 / 6113 (27.19%)	851 / 3057 (27.84%)	
number of deaths (all causes)	255	127	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal Neoplasm			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma Gastric			

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Adenocarcinoma Of Colon		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma Pancreas		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Adrenal Adenoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal Cell Carcinoma		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign Bone Neoplasm		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Cancer		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Neoplasm		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma Recurrent		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder Transitional Cell Carcinoma Stage Ii</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone Cancer</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain Cancer Metastatic</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Brain Neoplasm</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Brain Neoplasm Malignant</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast Cancer</b>		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast Cancer Metastatic</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast Cancer Stage Ii</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast Neoplasm</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchial Carcinoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Burkitt's Lymphoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Carcinoid Tumour Of The Duodenum</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix Carcinoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cervix Carcinoma Recurrent</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix Carcinoma Stage I</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic Lymphocytic Leukaemia</b>		

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear Cell Renal Cell Carcinoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Adenoma		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Cancer		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon Neoplasm		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse Large B-Cell Lymphoma		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial Adenocarcinoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial Cancer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid Tumour		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder Adenocarcinoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Adenoma		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Neoplasm		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Carcinoma		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Neoplasm		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal Stromal Tumour		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma Multiforme		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic Cancer		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hepatocellular Carcinoma</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Intraductal Papillary Mucinous Neoplasm</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Kaposi's Sarcoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Leiomyosarcoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Leukaemia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Lipoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lung Adenocarcinoma</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lung Cancer Metastatic</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Lung Carcinoma Cell Type Unspecified Recurrent		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage Iv		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung Neoplasm		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Neoplasm Malignant		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Lymphoma		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Melanoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Neoplasm Of Eye		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant Neoplasm Of Renal Pelvis		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant Pleural Effusion</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant Respiratory Tract Neoplasm</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Mantle Cell Lymphoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinum Neoplasm</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesothelioma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases To Central Nervous System</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases To Lung</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic Carcinoma Of The Bladder</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Metastatic Neoplasm</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Neoplasm Malignant</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Neoplasm Of Thymus</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neoplasm Prostate</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuroendocrine Tumour</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal Marginal Zone B-Cell Lymphoma</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-Small Cell Lung Cancer</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Non-Small Cell Lung Cancer Recurrent</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal Carcinoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Ovarian Cancer</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Ovarian Epithelial Cancer</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pancreatic Carcinoma</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Pancreatic Carcinoma Metastatic</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pancreatic Neuroendocrine Tumour</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Papillary Thyroid Cancer</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid Tumour Benign		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma Cell Myeloma		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate Cancer		
subjects affected / exposed	17 / 6113 (0.28%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 17	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Prostate Cancer Metastatic		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal Adenocarcinoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal Cancer		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal Cell Carcinoma		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal Neoplasm		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal Cancer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary Gland Adenoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary Gland Cancer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small Cell Lung Cancer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Small Intestine Carcinoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous Cell Carcinoma		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Superficial Spreading Melanoma Stage Unspecified		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular Neoplasm		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional Cell Carcinoma			
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Cancer			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm Ruptured			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic Aneurysm			
subjects affected / exposed	1 / 6113 (0.02%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Aneurysm Rupture			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic Stenosis			
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Thrombosis			

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arterial Occlusive Disease</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arterial Stenosis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriosclerosis</b>		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Circulatory Collapse</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Deep Vein Thrombosis</b>		
subjects affected / exposed	12 / 6113 (0.20%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Essential Hypertension</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Extremity Necrosis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Femoral Artery Occlusion</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma</b>		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertension</b>		
subjects affected / exposed	7 / 6113 (0.11%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hypertensive Crisis</b>		
subjects affected / exposed	9 / 6113 (0.15%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hypertensive Emergency</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypotension</b>		
subjects affected / exposed	2 / 6113 (0.03%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypovolaemic Shock</b>		
subjects affected / exposed	4 / 6113 (0.07%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
<b>Infarction</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intra-Abdominal Haematoma</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic Hypotension		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease		
subjects affected / exposed	7 / 6113 (0.11%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral Artery Aneurysm		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Stenosis		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Artery Thrombosis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Embolism		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Ischaemia		

subjects affected / exposed	11 / 6113 (0.18%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 15	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral Vascular Disorder		
subjects affected / exposed	12 / 6113 (0.20%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 13	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis Deep		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Thrombotic Syndrome		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Shock Haemorrhagic		
subjects affected / exposed	5 / 6113 (0.08%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Subclavian Artery Stenosis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal Arteritis		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboangiitis Obliterans			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis Superficial			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicophlebitis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose Ulceration			
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Insufficiency			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Thrombosis			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Thrombosis Limb			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Artificial Urinary Sphincter Implant			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Pacemaker Battery Replacement</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardioversion</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebrospinal Fluid Drainage</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hip Arthroplasty</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incisional Drainage</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Knee Arthroplasty</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Knee Operation</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Leg Amputation</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metatarsal Excision</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Parathyroidectomy</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Rehabilitation Therapy</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tooth Extraction</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>General disorders and administration site conditions</b>			
<b>Asthenia</b>			
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Catheter Site Haemorrhage</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Chest Discomfort</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Chest Pain</b>			

subjects affected / exposed	50 / 6113 (0.82%)	19 / 3057 (0.62%)
occurrences causally related to treatment / all	0 / 56	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Death</b>		
subjects affected / exposed	8 / 6113 (0.13%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 8	0 / 6
<b>Device Dislocation</b>		
subjects affected / exposed	9 / 6113 (0.15%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Device Failure</b>		
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Device Issue</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Device Leakage</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Device Malfunction</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Device Occlusion</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Drug Interaction</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fatigue</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>General Physical Health Deterioration</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>General Symptom</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Generalised Oedema</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hernia Obstructive</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperthermia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impaired Healing</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Implant Site Haematoma</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inflammation</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malaise</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Medical Device Complication</b>		
subjects affected / exposed	7 / 6113 (0.11%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multi-Organ Failure</b>		
subjects affected / exposed	4 / 6113 (0.07%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 4	0 / 1
<b>Non-Cardiac Chest Pain</b>		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema Peripheral</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain</b>		

subjects affected / exposed	2 / 6113 (0.03%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Patient-Device Incompatibility		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perforated Ulcer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyp		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	5 / 6113 (0.08%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Pain		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-Graft Endoleak		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden Cardiac Death		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Sudden Death		

subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
<b>Surgical Failure</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Systemic Inflammatory Response Syndrome</b>			
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Immune system disorders</b>			
<b>Anaphylactic Reaction</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaphylactic Shock</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device Allergy</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Food Allergy</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Secondary Immunodeficiency</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			

Benign Prostatic Hyperplasia			
subjects affected / exposed	8 / 6113 (0.13%)	5 / 3057 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Enlargement			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female Genital Tract Fistula			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital Prolapse			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cyst			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal Haemorrhage			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uterine Haemorrhage</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vaginal Haemorrhage</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vaginal Prolapse</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Acute Pulmonary Oedema</b>			
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acute Respiratory Distress Syndrome</b>			
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Acute Respiratory Failure</b>			
subjects affected / exposed	23 / 6113 (0.38%)	10 / 3057 (0.33%)	
occurrences causally related to treatment / all	0 / 29	0 / 12	
deaths causally related to treatment / all	0 / 4	0 / 3	
<b>Alveolitis Allergic</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Apnoea</b>			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aspiration		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma		
subjects affected / exposed	18 / 6113 (0.29%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 23	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis Chronic		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease		
subjects affected / exposed	84 / 6113 (1.37%)	51 / 3057 (1.67%)
occurrences causally related to treatment / all	0 / 121	0 / 71
deaths causally related to treatment / all	0 / 5	0 / 3
Chronic Respiratory Failure		

subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Dyspnoea</b>		
subjects affected / exposed	12 / 6113 (0.20%)	15 / 3057 (0.49%)
occurrences causally related to treatment / all	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Dyspnoea Exertional</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Emphysema</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epistaxis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemoptysis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydropneumothorax</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoxia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Idiopathic Pulmonary Fibrosis</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Interstitial Lung Disease</b>		
subjects affected / exposed	6 / 6113 (0.10%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Lung Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Lung Hernia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinal Disorder</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mediastinal Haemorrhage</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obstructive Airways Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pleural Effusion</b>		
subjects affected / exposed	21 / 6113 (0.34%)	10 / 3057 (0.33%)
occurrences causally related to treatment / all	0 / 22	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pleuritic Pain</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia Aspiration		
subjects affected / exposed	4 / 6113 (0.07%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonitis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	5 / 6113 (0.08%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Congestion		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Embolism		
subjects affected / exposed	23 / 6113 (0.38%)	17 / 3057 (0.56%)
occurrences causally related to treatment / all	0 / 23	0 / 17
deaths causally related to treatment / all	0 / 4	0 / 2
Pulmonary Fibrosis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Hypertension		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary Microemboli		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary Oedema</b>		
subjects affected / exposed	6 / 6113 (0.10%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Respiratory Acidosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Respiratory Arrest</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Respiratory Disorder</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory Distress</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Respiratory Failure</b>		
subjects affected / exposed	16 / 6113 (0.26%)	12 / 3057 (0.39%)
occurrences causally related to treatment / all	0 / 18	0 / 15
deaths causally related to treatment / all	0 / 6	0 / 6
<b>Sinus Polyp</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sleep Apnoea Syndrome</b>		

subjects affected / exposed	4 / 6113 (0.07%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Status Asthmaticus</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tracheal Stenosis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychiatric disorders</b>			
<b>Alcohol Abuse</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Alcohol Withdrawal Syndrome</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Completed Suicide</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Conversion Disorder</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Delirium</b>			
subjects affected / exposed	2 / 6113 (0.03%)	4 / 3057 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Depression</b>			

subjects affected / exposed	4 / 6113 (0.07%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Drug Dependence</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impaired Self-Care</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Major Depression</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental Disorder</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental Status Changes</b>		
subjects affected / exposed	4 / 6113 (0.07%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Panic Attack</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psychotic Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Schizoaffective Disorder</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Ideation			
subjects affected / exposed	0 / 6113 (0.00%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide Attempt			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Anticoagulation Drug Level Above Therapeutic			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration Bronchial			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatinine Increased			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Potassium Decreased			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon Dioxide Abnormal			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac Pacemaker Evaluation		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulation Time Prolonged		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram St Segment Elevation		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza A Virus Test Positive		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International Normalised Ratio Increased		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oxygen Saturation Decreased		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prothrombin Time Abnormal		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transaminases Increased		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine Output Decreased			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal Wound Dehiscence			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental Overdose			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Poisoning			
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Postoperative			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal Bite			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle Fracture			
subjects affected / exposed	4 / 6113 (0.07%)	4 / 3057 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Injury			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder Injury</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone Fissure</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Procedure Complication</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervical Vertebral Fracture</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chemical Poisoning</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Concussion</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Contusion</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary Artery Restenosis</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Craniocerebral Injury</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dislocation Of Vertebra</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dural Tear</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Exposure To Toxic Agent</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Extradural Haematoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Facial Bones Fracture</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fall</b>		
subjects affected / exposed	17 / 6113 (0.28%)	7 / 3057 (0.23%)
occurrences causally related to treatment / all	0 / 18	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fat Embolism</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Femur Fracture</b>			
subjects affected / exposed	11 / 6113 (0.18%)	4 / 3057 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Femoral Neck Fracture</b>			
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Foot Fracture</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Forearm Fracture</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Head Injury</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Heat Exhaustion</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Heat Stroke</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hip Fracture</b>			

subjects affected / exposed	8 / 6113 (0.13%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Humerus Fracture</b>		
subjects affected / exposed	4 / 6113 (0.07%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incisional Hernia</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Dislocation</b>		
subjects affected / exposed	12 / 6113 (0.20%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Dislocation Postoperative</b>		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Injury</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laceration</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ligament Injury</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ligament Rupture</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament Sprain		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb Injury		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower Limb Fracture		
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical Ventilation Complication		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Meniscus Injury		
subjects affected / exposed	0 / 6113 (0.00%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple Fractures		
subjects affected / exposed	0 / 6113 (0.00%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple Injuries		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Muscle Rupture		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle Strain</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Overdose</b>		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Patella Fracture</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic Fracture</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periprosthetic Fracture</b>		
subjects affected / exposed	6 / 6113 (0.10%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax Traumatic</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post Concussion Syndrome</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post Procedural Complication</b>		

subjects affected / exposed	18 / 6113 (0.29%)	11 / 3057 (0.36%)
occurrences causally related to treatment / all	0 / 18	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Post Procedural Discharge		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Haematoma		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Haematuria		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Haemorrhage		
subjects affected / exposed	3 / 6113 (0.05%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post Procedural Swelling		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Fever		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Ileus		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Respiratory Failure		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative Thoracic Procedure Complication		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Postoperative Wound Complication		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Haemorrhage		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Hypotension		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Nausea		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural Pain		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis Fracture		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radius Fracture		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal Laceration Postoperative</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Haematoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rib Fracture</b>		
subjects affected / exposed	2 / 6113 (0.03%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Road Traffic Accident</b>		
subjects affected / exposed	2 / 6113 (0.03%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Scrotal Haematoma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seroma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin Injury</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal Compression Fracture</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spinal Fracture</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Stab Wound</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Stress Fracture</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Subdural Haematoma</b>			
subjects affected / exposed	6 / 6113 (0.10%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Subdural Haemorrhage</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendon Rupture</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thermal Burn</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thoracic Vertebral Fracture</b>			

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia Fracture		
subjects affected / exposed	4 / 6113 (0.07%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity To Various Agents		
subjects affected / exposed	4 / 6113 (0.07%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheostomy Malfunction		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Arthritis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic Intracranial Haemorrhage		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper Limb Fracture		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral Injury		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral Stricture Postoperative		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Bypass Dysfunction			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Graft Occlusion			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Graft Thrombosis			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Pseudoaneurysm			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Dehiscence			
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist Fracture			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Anophthalmos			

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac Septal Defect</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ectopic Ureter</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hydrocele</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
<b>Acute Coronary Syndrome</b>			
subjects affected / exposed	13 / 6113 (0.21%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 15	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Acute Myocardial Infarction</b>			
subjects affected / exposed	56 / 6113 (0.92%)	22 / 3057 (0.72%)	
occurrences causally related to treatment / all	0 / 59	1 / 24	
deaths causally related to treatment / all	0 / 28	0 / 9	
<b>Angina Pectoris</b>			
subjects affected / exposed	19 / 6113 (0.31%)	10 / 3057 (0.33%)	
occurrences causally related to treatment / all	0 / 20	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Angina Unstable</b>			
subjects affected / exposed	27 / 6113 (0.44%)	9 / 3057 (0.29%)	
occurrences causally related to treatment / all	0 / 32	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic Valve Incompetence</b>			

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Aortic Valve Stenosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arrhythmia</b>		
subjects affected / exposed	9 / 6113 (0.15%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arrhythmia Supraventricular</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriosclerosis Coronary Artery</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Fibrillation</b>		
subjects affected / exposed	42 / 6113 (0.69%)	14 / 3057 (0.46%)
occurrences causally related to treatment / all	0 / 53	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Flutter</b>		
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Tachycardia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial Thrombosis</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular Block</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular Block Complete</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradyarrhythmia</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradycardia</b>		
subjects affected / exposed	5 / 6113 (0.08%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bundle Branch Block Left</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Arrest</b>		
subjects affected / exposed	10 / 6113 (0.16%)	8 / 3057 (0.26%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 4
<b>Cardiac Disorder</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cardiac Failure</b>		

subjects affected / exposed	34 / 6113 (0.56%)	16 / 3057 (0.52%)
occurrences causally related to treatment / all	0 / 40	0 / 36
deaths causally related to treatment / all	0 / 2	0 / 3
<b>Cardiac Failure Acute</b>		
subjects affected / exposed	16 / 6113 (0.26%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 22	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cardiac Failure Chronic</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Failure Congestive</b>		
subjects affected / exposed	69 / 6113 (1.13%)	29 / 3057 (0.95%)
occurrences causally related to treatment / all	1 / 102	0 / 37
deaths causally related to treatment / all	0 / 8	0 / 3
<b>Cardiac Tamponade</b>		
subjects affected / exposed	6 / 6113 (0.10%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac Valve Disease</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cardio-Respiratory Arrest</b>		
subjects affected / exposed	10 / 6113 (0.16%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 9	0 / 2
<b>Cardiogenic Shock</b>		
subjects affected / exposed	8 / 6113 (0.13%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 2
<b>Cardiomyopathy</b>		

subjects affected / exposed	5 / 6113 (0.08%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	1 / 6	0 / 1
deaths causally related to treatment / all	1 / 2	0 / 0
<b>Cardiopulmonary Failure</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiorenal Syndrome</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cor Pulmonale</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary Artery Disease</b>		
subjects affected / exposed	22 / 6113 (0.36%)	7 / 3057 (0.23%)
occurrences causally related to treatment / all	0 / 23	1 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Coronary Artery Occlusion</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary Artery Stenosis</b>		
subjects affected / exposed	7 / 6113 (0.11%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary Artery Thrombosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Heart Valve Incompetence</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive Heart Disease</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intracardiac Thrombus</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic Cardiomyopathy</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Left Ventricular Failure</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral Valve Incompetence</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial Infarction</b>		
subjects affected / exposed	27 / 6113 (0.44%)	16 / 3057 (0.52%)
occurrences causally related to treatment / all	0 / 27	0 / 16
deaths causally related to treatment / all	0 / 19	0 / 6
<b>Myocardial Ischaemia</b>		
subjects affected / exposed	8 / 6113 (0.13%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	1 / 8	0 / 3
deaths causally related to treatment / all	1 / 2	0 / 0
<b>Palpitations</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial Effusion		
subjects affected / exposed	5 / 6113 (0.08%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal Angina		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless Electrical Activity		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reperfusion Arrhythmia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Right Ventricular Failure		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sick Sinus Syndrome		
subjects affected / exposed	2 / 6113 (0.03%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial Block		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus Bradycardia		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress Cardiomyopathy		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular Tachyarrhythmia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular Tachycardia		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid Valve Incompetence		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricle Rupture		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular Arrhythmia</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular Fibrillation</b>			
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Ventricular Tachycardia</b>			
subjects affected / exposed	5 / 6113 (0.08%)	4 / 3057 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nervous system disorders</b>			
<b>Altered State Of Consciousness</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Apallic Syndrome</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arachnoid Cyst</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ataxia</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Brain Stem Stroke</b>			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid Arteriosclerosis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid Artery Stenosis		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal Tunnel Syndrome		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Artery Stenosis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Haemorrhage		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebral Infarction		
subjects affected / exposed	5 / 6113 (0.08%)	7 / 3057 (0.23%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 1
Cerebral Ischaemia		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral Thrombosis		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular Accident		
subjects affected / exposed	19 / 6113 (0.31%)	8 / 3057 (0.26%)
occurrences causally related to treatment / all	0 / 20	0 / 8
deaths causally related to treatment / all	0 / 5	0 / 2
Cerebrovascular Disorder		
subjects affected / exposed	3 / 6113 (0.05%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Cervical Myelopathy		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial Syndrome		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic Inflammatory Demyelinating Polyradiculoneuropathy		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Convulsion		
subjects affected / exposed	11 / 6113 (0.18%)	9 / 3057 (0.29%)
occurrences causally related to treatment / all	0 / 15	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Critical Illness Polyneuropathy		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's Type		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia With Lewy Bodies		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Neuropathy		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	4 / 6113 (0.07%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness Postural		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic Stroke		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	5 / 6113 (0.08%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		

subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Facial Paresis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhage Intracranial</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemorrhagic Stroke</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Headache</b>		
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemiplegic Migraine</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic Encephalopathy</b>		
subjects affected / exposed	2 / 6113 (0.03%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Hydrocephalus</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive Encephalopathy</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic Encephalopathy		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-Ischaemic Encephalopathy		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Intercostal Neuralgia		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial Aneurysm		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial Pressure Increased		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Cerebral Infarction		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic Stroke		

subjects affected / exposed	11 / 6113 (0.18%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	0 / 13	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Lacunar Infarction</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar Radiculopathy</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic Encephalopathy</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Migraine</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuropathy Peripheral</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Normal Pressure Hydrocephalus</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paraesthesia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Partial Seizures</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumocephalus		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Polyneuropathy		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post-Traumatic Headache		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular Pain		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular Syndrome		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal Cord Compression		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Status Epilepticus		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid Haemorrhage		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Syncope		
subjects affected / exposed	14 / 6113 (0.23%)	9 / 3057 (0.29%)
occurrences causally related to treatment / all	0 / 15	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Tension Headache		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamus Haemorrhage		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic Encephalopathy		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient Global Amnesia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient Ischaemic Attack		
subjects affected / exposed	21 / 6113 (0.34%)	8 / 3057 (0.26%)
occurrences causally related to treatment / all	0 / 21	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Trigeminal Neuralgia</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertebrobasilar Insufficiency</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo Cns Origin</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vocal Cord Paralysis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	19 / 6113 (0.31%)	11 / 3057 (0.36%)	
occurrences causally related to treatment / all	0 / 20	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Antiphospholipid Syndrome</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Coagulopathy</b>			
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Haemolytic Anaemia</b>			

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Haemorrhagic Anaemia</b>			
subjects affected / exposed	2 / 6113 (0.03%)	5 / 3057 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Iron Deficiency Anaemia</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Microcytic Anaemia</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nephrogenic Anaemia</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Normochromic Normocytic Anaemia</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thrombocytosis</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ear and labyrinth disorders</b>			
Deafness Neurosensory			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's Disease			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sudden Hearing Loss</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo</b>			
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertigo Positional</b>			
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eye disorders</b>			
<b>Amaurosis</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Amaurosis Fugax</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aphakia</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cataract</b>			
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Conjunctivochalasis</b>			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid Ptosis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phacolytic Glaucoma			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pterygium			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Detachment			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Vein Occlusion			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Haemorrhage			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Adhesions			

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Abdominal Hernia</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal Pain</b>		
subjects affected / exposed	14 / 6113 (0.23%)	11 / 3057 (0.36%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal Pain Lower</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal Pain Upper</b>		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal Wall Haematoma</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anal Fissure</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anal Fistula</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ascites</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Change Of Bowel Habit		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colitis		
subjects affected / exposed	5 / 6113 (0.08%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis Ischaemic		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis Microscopic		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic Pseudo-Obstruction		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic Stenosis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	9 / 6113 (0.15%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's Disease		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dental Pulp Disorder		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Gastroparesis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic Hernia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	8 / 6113 (0.13%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	1 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Diverticular Perforation		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulum		
subjects affected / exposed	4 / 6113 (0.07%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal Ulcer Haemorrhage		

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspepsia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Enterovesical Fistula</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erosive Duodenitis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erosive Oesophagitis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Faecaloma</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Food Poisoning</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastric Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastric Haemorrhage</b>		

subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Ulcer		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Ulcer Haemorrhage		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric Ulcer Perforation		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastritis		
subjects affected / exposed	8 / 6113 (0.13%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis Erosive		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal Ulcer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis Haemorrhagic		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal Amyloidosis		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal Haemorrhage</b>		
subjects affected / exposed	13 / 6113 (0.21%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Gastrointestinal Hypomotility</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal Obstruction</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrooesophageal Reflux Disease</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematemesis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Haemorrhoids</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hernial Eventration</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiatus Hernia</b>		

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileal Stenosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus</b>		
subjects affected / exposed	6 / 6113 (0.10%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus Paralytic</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impaired Gastric Emptying</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inguinal Hernia</b>		
subjects affected / exposed	4 / 6113 (0.07%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Inguinal Hernia, Obstructive</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal Haemorrhage</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal Obstruction</b>		

subjects affected / exposed	6 / 6113 (0.10%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal Perforation</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intra-Abdominal Haemorrhage</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Large Intestinal Obstruction</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Large Intestine Polyp</b>		
subjects affected / exposed	5 / 6113 (0.08%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower Gastrointestinal Haemorrhage</b>		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Melaena</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric Artery Thrombosis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesenteric Vein Thrombosis</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nausea</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal Obstruction</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Oesophageal Stenosis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal Varices Haemorrhage</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophagitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oral Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatic Pseudocyst</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis</b>		

subjects affected / exposed	6 / 6113 (0.10%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis Acute</b>		
subjects affected / exposed	4 / 6113 (0.07%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis Chronic</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis Relapsing</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic Ulcer</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periodontal Disease</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritoneal Adhesions</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritoneal Haemorrhage</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Proctalgia</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal Haemorrhage</b>		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal Prolapse</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Small Intestinal Obstruction</b>		
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spigelian Hernia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subileus</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thrombosis Mesenteric Vessel</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Umbilical Hernia</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Umbilical Hernia, Obstructive</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Varices Oesophageal			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile Duct Obstruction			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stenosis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stone			
subjects affected / exposed	3 / 6113 (0.05%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			

subjects affected / exposed	2 / 6113 (0.03%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholangitis Acute</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis</b>		
subjects affected / exposed	7 / 6113 (0.11%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis Acute</b>		
subjects affected / exposed	2 / 6113 (0.03%)	7 / 3057 (0.23%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis Chronic</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholelithiasis</b>		
subjects affected / exposed	7 / 6113 (0.11%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cirrhosis Alcoholic</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gallbladder Polyp</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic Cirrhosis</b>		

subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatic Cyst</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatic Failure</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
<b>Hepatitis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatitis Acute</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatorenal Syndrome</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hydrocholecystis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin and subcutaneous tissue disorders</b>			
<b>Angioedema</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Decubitus Ulcer</b>			

subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis Contact		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Foot		
subjects affected / exposed	24 / 6113 (0.39%)	13 / 3057 (0.43%)
occurrences causally related to treatment / all	0 / 25	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Ulcer		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ecchymosis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hidradenitis		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash Erythematous		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin Necrosis</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Skin Ulcer</b>			
subjects affected / exposed	11 / 6113 (0.18%)	7 / 3057 (0.23%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Stevens-Johnson Syndrome</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Azotaemia</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
<b>Bladder Mass</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder Neck Obstruction</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder Outlet Obstruction</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus Ureteric</b>			

subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus Urinary		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis Interstitial		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic Nephropathy		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	8 / 6113 (0.13%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lupus Nephritis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Micturition Disorder		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		

subjects affected / exposed	9 / 6113 (0.15%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrotic Syndrome</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obstructive Uropathy</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Proteinuria</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Failure</b>		
subjects affected / exposed	7 / 6113 (0.11%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Renal Failure Acute</b>		
subjects affected / exposed	31 / 6113 (0.51%)	8 / 3057 (0.26%)
occurrences causally related to treatment / all	0 / 35	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Renal Failure Chronic</b>		
subjects affected / exposed	17 / 6113 (0.28%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 19	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0
<b>Renal Haemorrhage</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Impairment</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Injury</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Tubular Necrosis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Strangury</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stress Urinary Incontinence</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tubulointerstitial Nephritis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ureteric Stenosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urethral Stenosis</b>		
subjects affected / exposed	7 / 6113 (0.11%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary Incontinence</b>		

subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesicocutaneous Fistula			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism Primary			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Mass			

subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Ankylosing Spondylitis</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Arthralgia</b>			
subjects affected / exposed	10 / 6113 (0.16%)	4 / 3057 (0.13%)	
occurrences causally related to treatment / all	0 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis</b>			
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthrofibrosis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthropathy</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Back Pain</b>			
subjects affected / exposed	8 / 6113 (0.13%)	8 / 3057 (0.26%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bursitis</b>			
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cervical Spinal Stenosis</b>			

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chondropathy</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic Recurrent Multifocal Osteomyelitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Collagen Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Costochondritis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fistula</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Exostosis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Foot Deformity</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fracture Nonunion</b>		

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gouty Arthritis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Disc Degeneration</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Disc Disorder</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Disc Protrusion</b>		
subjects affected / exposed	4 / 6113 (0.07%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Instability</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Swelling</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar Spinal Stenosis</b>		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mobility Decreased</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle Necrosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle Spasms</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal Chest Pain</b>		
subjects affected / exposed	5 / 6113 (0.08%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal Pain</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neck Pain</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoarthritis</b>		

subjects affected / exposed	47 / 6113 (0.77%)	19 / 3057 (0.62%)
occurrences causally related to treatment / all	0 / 51	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain In Extremity</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pseudarthrosis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psoriatic Arthropathy</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhabdomyolysis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0
<b>Rotator Cuff Syndrome</b>		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scoliosis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal Column Stenosis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylitis</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spinal Osteoarthritis</b>			
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spondylolisthesis</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendonitis</b>			
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tenosynovitis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal Hernia Gangrenous</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal Infection</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal Sepsis</b>			
subjects affected / exposed	2 / 6113 (0.03%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Abdominal Wall Abscess</b>			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess</b>		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess Limb</b>		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anal Abscess</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis</b>		
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis Perforated</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriovenous Graft Site Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis Bacterial</b>		
subjects affected / exposed	11 / 6113 (0.18%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis Infective</b>		

subjects affected / exposed	8 / 6113 (0.13%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Asymptomatic Bacteriuria</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atypical Mycobacterial Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		
subjects affected / exposed	8 / 6113 (0.13%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial Sepsis</b>		
subjects affected / exposed	4 / 6113 (0.07%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial Tracheitis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Beta Haemolytic Streptococcal Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary Sepsis</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast Cellulitis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	11 / 6113 (0.18%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Bronchopneumonia</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bursitis Infective</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Candida Sepsis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cellulitis</b>		
subjects affected / exposed	63 / 6113 (1.03%)	36 / 3057 (1.18%)
occurrences causally related to treatment / all	1 / 78	0 / 41
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic Hepatitis C</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Clostridium Difficile Colitis</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Clostridium Difficile Infection</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dengue Fever</b>		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dermo-Hypodermatitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Device Related Infection</b>		
subjects affected / exposed	18 / 6113 (0.29%)	12 / 3057 (0.39%)
occurrences causally related to treatment / all	0 / 22	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Diabetic Foot Infection</b>		
subjects affected / exposed	26 / 6113 (0.43%)	9 / 3057 (0.29%)
occurrences causally related to treatment / all	0 / 30	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Diabetic Gangrene</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diarrhoea Infectious</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated Tuberculosis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diverticulitis		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis Bacterial		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter Pneumonia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis Bacterial		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis Infectious		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erysipelas</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia Bacteraemia</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia Sepsis</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia Urinary Tract Infection</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gangrene</b>		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastric Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis</b>		
subjects affected / exposed	10 / 6113 (0.16%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis Viral</b>		

subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Genital Herpes</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Graft Infection</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Groin Abscess</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic Cyst Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes Virus Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes Zoster</b>		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Implant Site Infection</b>		

subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incision Site Infection		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected Skin Ulcer		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infection In An Immunocompromised Host		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective Exacerbation Of Bronchiectasis		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective Exacerbation Of Chronic Obstructive Airways Disease		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective Spondylitis		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		

subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral Discitis</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Kidney Infection</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Liver Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lobar Pneumonia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Localised Infection</b>		
subjects affected / exposed	4 / 6113 (0.07%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower Respiratory Tract Infection</b>		
subjects affected / exposed	7 / 6113 (0.11%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower Respiratory Tract Infection Viral</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung Infection		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	4 / 6113 (0.07%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mumps		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mycobacterium Avium Complex Infection		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nail Infection		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurological Infection		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosyphilis		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orchitis</b>		
subjects affected / exposed	6 / 6113 (0.10%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis</b>		
subjects affected / exposed	27 / 6113 (0.44%)	11 / 3057 (0.36%)
occurrences causally related to treatment / all	0 / 29	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis Acute</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis Chronic</b>		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis Externa</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paraspinal Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paronychia</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Perihepatic Abscess</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Perineal Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periodontitis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonitis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonsillar Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia</b>		
subjects affected / exposed	107 / 6113 (1.75%)	67 / 3057 (2.19%)
occurrences causally related to treatment / all	0 / 122	0 / 84
deaths causally related to treatment / all	0 / 7	0 / 9
<b>Pneumonia Bacterial</b>		
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Pneumonia Necrotising</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia Pneumococcal</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia Staphylococcal</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Poliomyelitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post Procedural Cellulitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post Procedural Infection</b>		
subjects affected / exposed	7 / 6113 (0.11%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post Procedural Pneumonia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post Procedural Sepsis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Postoperative Wound Infection</b>		
subjects affected / exposed	28 / 6113 (0.46%)	15 / 3057 (0.49%)
occurrences causally related to treatment / all	0 / 30	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prostatic Abscess</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psoas Abscess</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary Sepsis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Pulmonary Tuberculosis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis</b>		
subjects affected / exposed	5 / 6113 (0.08%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis Acute</b>		
subjects affected / exposed	7 / 6113 (0.11%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal Abscess</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory Tract Infection</b>		
subjects affected / exposed	7 / 6113 (0.11%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Scrotal Abscess</b>		

subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	34 / 6113 (0.56%)	18 / 3057 (0.59%)
occurrences causally related to treatment / all	0 / 38	0 / 18
deaths causally related to treatment / all	0 / 5	0 / 5
<b>Septic Arthritis Staphylococcal</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Septic Shock</b>		
subjects affected / exposed	26 / 6113 (0.43%)	13 / 3057 (0.43%)
occurrences causally related to treatment / all	0 / 27	0 / 13
deaths causally related to treatment / all	0 / 21	0 / 8
<b>Sinusitis Bacterial</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin Bacterial Infection</b>		
subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin Infection</b>		
subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft Tissue Infection</b>		
subjects affected / exposed	3 / 6113 (0.05%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Staphylococcal Bacteraemia</b>		

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Staphylococcal Infection</b>		
subjects affected / exposed	4 / 6113 (0.07%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Staphylococcal Osteomyelitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Staphylococcal Sepsis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Subcutaneous Abscess</b>		
subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tracheitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tracheobronchitis</b>		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tuberculosis</b>		
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Upper Respiratory Tract Infection</b>		

subjects affected / exposed	1 / 6113 (0.02%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Bladder Abscess		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Tract Infection		
subjects affected / exposed	91 / 6113 (1.49%)	38 / 3057 (1.24%)
occurrences causally related to treatment / all	0 / 116	0 / 47
deaths causally related to treatment / all	0 / 1	0 / 0
Urinary Tract Infection Bacterial		
subjects affected / exposed	3 / 6113 (0.05%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary Tract Infection Pseudomonal		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	11 / 6113 (0.18%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0
Viral Infection		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral Upper Respiratory Tract Infection		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound Infection		

subjects affected / exposed	5 / 6113 (0.08%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection Bacterial			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Central Obesity			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased Appetite			
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	5 / 6113 (0.08%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus			
subjects affected / exposed	12 / 6113 (0.20%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 15	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	8 / 6113 (0.13%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 11	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Complication			

subjects affected / exposed	2 / 6113 (0.03%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Diabetic Ketoacidosis</b>		
subjects affected / exposed	3 / 6113 (0.05%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Electrolyte Imbalance</b>		
subjects affected / exposed	2 / 6113 (0.03%)	3 / 3057 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fluid Overload</b>		
subjects affected / exposed	4 / 6113 (0.07%)	5 / 3057 (0.16%)
occurrences causally related to treatment / all	1 / 6	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gout</b>		
subjects affected / exposed	5 / 6113 (0.08%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperamylasaemia</b>		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypercalcaemia</b>		
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperglycaemia</b>		
subjects affected / exposed	10 / 6113 (0.16%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperglycaemic Hyperosmolar Nonketotic Syndrome</b>		

subjects affected / exposed	3 / 6113 (0.05%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	5 / 6113 (0.08%)	4 / 3057 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperuricaemia		
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	11 / 6113 (0.18%)	6 / 3057 (0.20%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	2 / 6113 (0.03%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	6 / 6113 (0.10%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	0 / 6113 (0.00%)	1 / 3057 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		

subjects affected / exposed	0 / 6113 (0.00%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metabolic Acidosis</b>			
subjects affected / exposed	0 / 6113 (0.00%)	3 / 3057 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
<b>Obesity</b>			
subjects affected / exposed	2 / 6113 (0.03%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Type 1 Diabetes Mellitus</b>			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Type 2 Diabetes Mellitus</b>			
subjects affected / exposed	1 / 6113 (0.02%)	2 / 3057 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	C. Difficile Vaccine Group	Placebo Group	
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	1347 / 6113 (22.04%)	401 / 3057 (13.12%)	
<b>Nervous system disorders</b>			
Headache			
subjects affected / exposed	531 / 6113 (8.69%)	229 / 3057 (7.49%)	
occurrences (all)	758	327	
<b>General disorders and administration site conditions</b>			
Injection Site Pain			
subjects affected / exposed	855 / 6113 (13.99%)	127 / 3057 (4.15%)	
occurrences (all)	1252	157	

Malaise subjects affected / exposed occurrences (all)	325 / 6113 (5.32%) 456	135 / 3057 (4.42%) 195	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	345 / 6113 (5.64%) 481	146 / 3057 (4.78%) 205	
Myalgia subjects affected / exposed occurrences (all)	368 / 6113 (6.02%) 556	132 / 3057 (4.32%) 201	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 March 2013	Following amendments were made:1) European Union Drug Regulating Authorities Clinical Trials (Eudra CT) number added for clinical trial identification required for clinical trial agreement (CTA) submissions, 2) Sponsor's Responsible Medical Officer changed from Ginamarie Foglia to Guy de Bruyn, 3) Clarified the number of subjects in each of the subsets (immunogenicity and reactogenicity) as part of the total enrolled subjects, 4) Added more information to define Risk Stratum 2 as subjects by specifying that they had to have an impending hospital stay planned to be $\geq 72$ hours, 5) Specified collection of AEs from Day 0 to Day 60 as "unsolicited" as per Center for Biologics and Research (CBER) comment provided 06 February 2013, 6) Added text to reinforce that only results from PCR testing performed by the central laboratory was used for analyses of primary efficacy endpoints, 7) Added secondary objectives as per CBER comment provided 08 February 2013 and redefined definition of severe CDI for secondary endpoints, 8) Exploratory objectives reworded and expanded to represent refinement of quality of life objectives , 9) Redefined statistical method explanation of the primary analysis and added statistical methods for the secondary and exploratory objectives as per CBER comment 06 February 2013, 10) Removed requirement for recording vomiting and constipation as symptoms that were tracked in this study, 11) Clarified role of Independent Data Monitoring Committee (IDMC) for the study, 12) Added text to reinforce description of the safety follow-up for at least 6 months after the last injection as per CBER 06 February 2013, 13) Added wording to clarify that some data required for CDI characterization would be obtained from medical records to complete the electronic case report form, 14) Redefined medication to be included in Categories 2 and 3 for concomitant medications.
24 July 2013	Following changes were made: 1) The abbreviation AIOH was removed and replaced by aluminum hydroxide, aluminum hydroxide adjuvant, or aluminum containing adjuvant depending on the context as per clarification requested by European Health Authorities, 2) Modification made to exclusion criteria 1 to explicitly define use of contraception or abstinence in response to European agency comments.
07 March 2014	Following changes were made: Inclusion criterion for Risk Stratum 1 changed from hospital stays lasting $\geq 72$ to stays lasting $\geq 24$ hours due to increasing pressure by global medical providers to limit hospital stays to less than 72 hours in an effort to increase enrollment.
28 May 2014	Following changes were made: 1) Change made in trial design to allow for continuous enrollment based on operational efficiency and no specific safety concerns cited at the time, 2) Clarified that subjects in immunogenicity subset would not provide information on reactogenicity.
23 June 2016	Following changes were made: 1) Adjustments made to interim analysis strategy, including clearly defining the approach statistically, to allow for Sponsor need for timely trial data and decision making, 2) Clarified the end of study procedures in the event of not reaching 250 CDI cases by completion of planned follow-up.

14 February 2017	Following changes were made: 1) Sample size increased by 10 percent (%) (from 15 000 to 16 500 subject) to compensate for subjects who had not received all 3 vaccinations due to an enrollment pause instituted on 14 July 2016, as well as, for replacing subjects who had early terminated voluntarily and created a higher than expected drop-out, 2) Trial timelines extended due to enrollment pause and vaccination suspension that began 14 July 2016 to allow for analysis of safety data by IDMC, 3) SAE collection was expanded from 6 months after last vaccination to through the end of the trial period and SAEs with an outcome of death or non-fatal SAEs leading to hospitalization were to be submitted for review and adjudicated by a blinded external committee as per IDMC recommendation on 09 January 2017.
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Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
14 July 2016	Sanofi Pasteur paused the enrollment and further vaccination in the trial to investigate a potential safety concern, upon notification by the IDMC. Following further review in December 2016, the IDMC recommended that the trial resume enrollment without modification of the trial eligibility criteria.	10 January 2017
17 November 2017	Enrollment and vaccination were stopped upon recommendation from the IDMC following completion of the first interim analysis (50 cases of confirmed CDI observed), due to the low probability of achieving study objectives.	-

Notes:

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated because the IDMC concluded that the probability that the study will meet its primary objective was low.

Notes: