



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	• Correction of full data set Updated safety optional field

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 ≥ 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:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	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
Arm title	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).

Arm title	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).

Number of subjects in period 1	C. Difficile Vaccine Group	Placebo Group
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 ^[1]
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: ≥ 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 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 ≥ 38.5 degree Celsius ($^{\circ}\text{C}$), white blood cell count $\geq 15,000$ cells/ 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: ≥ 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 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	

End point values	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 ≥ 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 ≥ 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 ≥ 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
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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: ≥ 2 (n=433, 217)	93.3 (90.5 to 95.5)	0.9 (0.1 to 3.3)		
Toxin A IgG: ≥ 4 (n=433, 217)	88.9 (85.6 to 91.7)	0.0 (0.0 to 1.7)		
Toxin B IgG: ≥ 2 (n=433, 218)	82.2 (78.3 to 85.7)	4.6 (2.2 to 8.3)		
Toxin B IgG: ≥ 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
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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: ≥ 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 (PCR confirmed) primary CDI cases. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 0 and Day 60

End point values	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

End point values	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 ≥ 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 ≥ 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 ≥ 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

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 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

End point values	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
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: ≥ 25 to ≤ 50 mm, Grade 2: > 51 to ≤ 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
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	
Bladder Transitional Cell Carcinoma Stage Ii			
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	
Bone 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	
Brain Cancer Metastatic			
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	
Brain Neoplasm			
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	
Brain Neoplasm Malignant			
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	
Breast Cancer			
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	
Breast Cancer Metastatic			
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	
Breast Cancer Stage Ii			

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

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

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

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	
Metastatic Carcinoma Of The Bladder			
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	
Metastatic 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 / 1	
Neoplasm Malignant			
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	
Neoplasm Of Thymus			
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	
Neoplasm Prostate			
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	
Neuroendocrine 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	
Nodal Marginal Zone B-Cell Lymphoma			
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	
Non-Small Cell Lung Cancer			

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	
Non-Small Cell Lung Cancer Recurrent			
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	
Oesophageal 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	
Ovarian Cancer			
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	
Ovarian Epithelial 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	
Pancreatic 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 / 2	0 / 0	
Pancreatic Carcinoma 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	
Pancreatic Neuroendocrine Tumour			
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	
Papillary Thyroid 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	
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	
Arterial Occlusive 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	
Arterial Stenosis			
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	
Arteriosclerosis			
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	
Circulatory Collapse			
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	
Deep Vein Thrombosis			
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	
Essential Hypertension			
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	
Extremity Necrosis			
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	
Femoral Artery Occlusion			

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	
Haematoma			
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	
Hypertension			
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	
Hypertensive Crisis			
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	
Hypertensive Emergency			
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	
Hypotension			
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	
Hypovolaemic Shock			
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	
Infarction			
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	
Intra-Abdominal Haematoma			

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

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

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	
Death			
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	
Device Dislocation			
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	
Device Failure			
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	
Device Issue			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Leakage			
subjects affected / exposed	1 / 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	
Device 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	
Device Occlusion			
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	
Drug Interaction			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
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	
General Physical Health Deterioration			
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	
General Symptom			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised Oedema			
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	
Hernia Obstructive			
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	
Hyperthermia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired Healing			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant Site 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	
Inflammation			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
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	
Medical Device Complication			
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	
Multi-Organ Failure			
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	
Non-Cardiac Chest Pain			
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	
Oedema			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema Peripheral			
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	
Pain			

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

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	
Uterine 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	
Vaginal 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	
Vaginal Prolapse			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
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	
Acute Respiratory Distress Syndrome			
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	
Acute Respiratory Failure			
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	
Alveolitis Allergic			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apnoea			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Dyspnoea			
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	
Dyspnoea Exertional			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
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	
Haemoptysis			
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	
Hydropneumothorax			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic Pulmonary Fibrosis			

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	
Interstitial Lung Disease			
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	
Lung Disorder			
subjects affected / exposed	1 / 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	
Lung 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	
Mediastinal 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	
Mediastinal 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	
Obstructive Airways Disorder			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural Effusion			
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	
Pleuritic Pain			

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	
Pulmonary Oedema			
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	
Respiratory Acidosis			
subjects affected / exposed	1 / 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	
Respiratory Arrest			
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	
Respiratory 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	
Respiratory Distress			
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	
Respiratory Failure			
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	
Sinus Polyp			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep Apnoea Syndrome			

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	
Status Asthmaticus			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal Stenosis			
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	
Psychiatric disorders			
Alcohol Abuse			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Withdrawal Syndrome			
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	
Completed Suicide			
subjects affected / exposed	1 / 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	
Conversion Disorder			
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	
Delirium			
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	
Depression			

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	
Drug Dependence			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired Self-Care			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major Depression			
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	
Mental 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	
Mental Status Changes			
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	
Panic Attack			
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	
Psychotic Disorder			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective 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	
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	
Bladder 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	
Bone Fissure			
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	
Cardiac Procedure 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 / 0	
Cervical Vertebral 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	
Chemical Poisoning			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
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	
Contusion			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Restenosis			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral Injury			
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	
Dislocation Of Vertebra			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dural Tear			
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	
Exposure To Toxic Agent			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural 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	
Facial Bones 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	
Fall			
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	
Fat Embolism			

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	
Femur Fracture			
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	
Femoral Neck Fracture			
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	
Foot Fracture			
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	
Forearm Fracture			
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	
Head 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	
Heat Exhaustion			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat Stroke			
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	
Hip Fracture			

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	
Humerus 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	
Incisional Hernia			
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	
Joint Dislocation			
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	
Joint Dislocation Postoperative			
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	
Joint 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	
Laceration			
subjects affected / exposed	1 / 6113 (0.02%)	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 Injury			
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	
Ligament Rupture			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Muscle Strain			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
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	
Patella Fracture			
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	
Pelvic Fracture			
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	
Periprosthetic Fracture			
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	
Pneumothorax Traumatic			
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	
Post Concussion 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	
Post Procedural Complication			

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	
Rectal Laceration 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	
Renal 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	
Rib Fracture			
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	
Road Traffic Accident			
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	
Scrotal 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	
Seroma			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin 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	
Spinal Compression Fracture			

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	
Spinal Fracture			
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	
Stab 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 / 1	0 / 0	
Stress 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	
Subdural Haematoma			
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	
Subdural 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	
Tendon 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	
Thermal Burn			
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	
Thoracic Vertebral Fracture			

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	
Cardiac Septal Defect			
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	
Ectopic Ureter			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
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	
Cardiac disorders			
Acute Coronary Syndrome			
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	
Acute Myocardial Infarction			
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	
Angina Pectoris			
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	
Angina Unstable			
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	
Aortic Valve Incompetence			

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	
Aortic Valve 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	
Arrhythmia			
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	
Arrhythmia Supraventricular			
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	
Arteriosclerosis Coronary Artery			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Fibrillation			
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	
Atrial Flutter			
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	
Atrial 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	
Atrial 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	
Atrioventricular Block			
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	
Atrioventricular Block Complete			
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	
Bradyarrhythmia			
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	
Bradycardia			
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	
Bundle Branch Block Left			
subjects affected / exposed	1 / 6113 (0.02%)	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 Arrest			
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	
Cardiac Disorder			
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	
Cardiac Failure			

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	
Cardiac Failure Acute			
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	
Cardiac Failure Chronic			
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	
Cardiac Failure Congestive			
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	
Cardiac Tamponade			
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	
Cardiac Valve 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 / 1	0 / 0	
Cardio-Respiratory Arrest			
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	
Cardiogenic Shock			
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	
Cardiomyopathy			

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	
Cardiopulmonary 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	
Cardiorenal 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	
Cor Pulmonale			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Disease			
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	
Coronary Artery 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	
Coronary Artery Stenosis			
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	
Coronary 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	
Heart Valve Incompetence			

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	
Hypertensive Heart 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	
Intracardiac Thrombus			
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	
Ischaemic Cardiomyopathy			
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	
Left 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	
Mitral Valve Incompetence			
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	
Myocardial Infarction			
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	
Myocardial Ischaemia			
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	
Palpitations			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Ventricular 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	
Ventricular Fibrillation			
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	
Ventricular Tachycardia			
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	
Nervous system disorders			
Altered State Of Consciousness			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apallic 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	
Arachnoid Cyst			
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	
Ataxia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Stem 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	
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	
Facial Paresis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage Intracranial			
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	
Haemorrhagic Stroke			
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	
Headache			
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	
Hemiplegic Migraine			
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	
Hepatic Encephalopathy			
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	
Hydrocephalus			
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	
Hypertensive 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	
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	
Lacunar 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	
Lumbar Radiculopathy			
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	
Metabolic 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	
Migraine			
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	
Neuropathy Peripheral			
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	
Normal Pressure Hydrocephalus			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial Seizures			

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	
Trigeminal 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	
Vertebrobasilar 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	
Vertigo Cns Origin			
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	
Vocal Cord Paralysis			
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	
Blood and lymphatic system disorders			
Anaemia			
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	
Antiphospholipid Syndrome			
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	
Coagulopathy			
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	
Haemolytic Anaemia			

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	
Haemorrhagic Anaemia			
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	
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic Anaemia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic Anaemia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic Normocytic Anaemia			
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	
Thrombocytosis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
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	
Sudden Hearing Loss			
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	
Vertigo			
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	
Vertigo Positional			
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	
Eye disorders			
Amaurosis			
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	
Amaurosis Fugax			
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	
Aphakia			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
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	
Conjunctivochalasis			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Abdominal Hernia			
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	
Abdominal Pain			
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	
Abdominal Pain Lower			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			
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	
Abdominal Wall Haematoma			
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	
Anal Fissure			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal 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	
Ascites			

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

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	
Gastrointestinal Haemorrhage			
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	
Gastrointestinal Hypomotility			
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	
Gastrointestinal 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	
Gastrooesophageal Reflux Disease			
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	
Haematemesis			
subjects affected / exposed	1 / 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	
Haemorrhoids			
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	
Hernial Eventration			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus Hernia			

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	
Ileal 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	
Ileus			
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	
Ileus Paralytic			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired Gastric Emptying			
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	
Inguinal Hernia			
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	
Inguinal Hernia, Obstructive			
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	
Intestinal Haemorrhage			
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	
Intestinal Obstruction			

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	
Intestinal Perforation			
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	
Intra-Abdominal 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	
Large Intestinal 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	
Large Intestine Polyp			
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	
Lower Gastrointestinal Haemorrhage			
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	
Melaena			
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	
Mesenteric Artery Thrombosis			
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	
Mesenteric Vein 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	
Nausea			
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	
Oesophageal 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 / 1	0 / 0	
Oesophageal 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	
Oesophageal Varices Haemorrhage			
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	
Oesophagitis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral Disorder			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Pseudocyst			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			

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	
Pancreatitis Acute			
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	
Pancreatitis Chronic			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Relapsing			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic 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	
Periodontal Disease			
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	
Peritoneal Adhesions			
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	
Peritoneal 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	
Proctalga			

subjects affected / exposed	1 / 6113 (0.02%)	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 Haemorrhage			
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	
Rectal Prolapse			
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	
Small Intestinal Obstruction			
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	
Spigelian 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	
Subileus			
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	
Thrombosis Mesenteric Vessel			
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	
Umbilical Hernia			
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	
Umbilical Hernia, Obstructive			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Cholangitis Acute			
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	
Cholecystitis			
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	
Cholecystitis Acute			
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	
Cholecystitis Chronic			
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	
Cholelithiasis			
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	
Cirrhosis Alcoholic			
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	
Gallbladder Polyp			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Cirrhosis			

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

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	
Skin Necrosis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Ulcer			
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	
Stevens-Johnson Syndrome			
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 and urinary disorders			
Azotaemia			
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	
Bladder Mass			
subjects affected / exposed	1 / 6113 (0.02%)	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 Neck 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	
Bladder Outlet Obstruction			
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	
Calculus Ureteric			

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	
Nephrotic Syndrome			
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	
Obstructive Uropathy			
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	
Proteinuria			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
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	
Renal Failure Acute			
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	
Renal Failure Chronic			
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	
Renal 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	
Renal Impairment			

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	
Renal 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	
Renal Tubular Necrosis			
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	
Strangury			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress Urinary Incontinence			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial Nephritis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric 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	
Urethral Stenosis			
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	
Urinary Incontinence			

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	
Musculoskeletal and connective tissue disorders			
Ankylosing Spondylitis			
subjects affected / exposed	1 / 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	
Arthralgia			
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	
Arthritis			
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	
Arthrofibrosis			
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	
Arthropathy			
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	
Back Pain			
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	
Bursitis			
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	
Cervical Spinal Stenosis			

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

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	
Gouty Arthritis			
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	
Intervertebral Disc Degeneration			
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	
Intervertebral Disc Disorder			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Protrusion			
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	
Joint Instability			
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	
Joint 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	
Lumbar Spinal Stenosis			
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	
Mobility 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	
Muscle Necrosis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Spasms			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Chest Pain			
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	
Musculoskeletal 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	
Myalgia			
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	
Neck Pain			
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	
Osteitis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			

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	
Pain In Extremity			
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	
Pseudarthrosis			
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	
Psoriatic Arthropathy			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
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	
Rotator Cuff Syndrome			
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	
Scoliosis			
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	
Spinal Column 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	
Spondylitis			

subjects affected / exposed	1 / 6113 (0.02%)	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 Osteoarthritis			
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	
Spondylolisthesis			
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	
Tendonitis			
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	
Tenosynovitis			
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	
Infections and infestations			
Abdominal Hernia Gangrenous			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal 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	
Abdominal Sepsis			
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	
Abdominal Wall 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	
Abscess			
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	
Abscess Limb			
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	
Anal Abscess			
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	
Appendicitis			
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	
Appendicitis Perforated			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous Graft Site 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	
Arthritis Bacterial			
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	
Arthritis Infective			

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	
Asymptomatic Bacteriuria			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical Mycobacterial 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	
Bacteraemia			
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	
Bacterial 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	
Bacterial Sepsis			
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	
Bacterial Tracheitis			
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	
Beta Haemolytic Streptococcal 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	
Biliary Sepsis			

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	
Breast 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	
Breast Cellulitis			
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			
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	
Bronchopneumonia			
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	
Bursitis Infective			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida Sepsis			
subjects affected / exposed	1 / 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	
Cellulitis			
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	
Chronic Hepatitis C			

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	
Clostridium Difficile Colitis			
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	
Clostridium Difficile Infection			
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	
Dengue Fever			
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	
Dermo-Hypodermatitis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Related Infection			
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	
Diabetic Foot Infection			
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	
Diabetic Gangrene			
subjects affected / exposed	1 / 6113 (0.02%)	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 Infectious			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Erysipelas			
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	
Escherichia Bacteraemia			
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	
Escherichia Sepsis			
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	
Escherichia Urinary Tract Infection			
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	
Gangrene			
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	
Gastric 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	
Gastroenteritis			
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	
Gastroenteritis Viral			

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

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	
Intervertebral Discitis			
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	
Joint 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	
Kidney 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	
Liver Abscess			
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	
Lobar 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	
Localised Infection			
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	
Lower Respiratory Tract Infection			
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	
Lower Respiratory Tract Infection Viral			

subjects affected / exposed	1 / 6113 (0.02%)	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	
Orchitis			
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	
Osteomyelitis			
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	
Osteomyelitis Acute			
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	
Osteomyelitis Chronic			
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	
Otitis Externa			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraspinal 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	
Paronychia			
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	
Perihepatic 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	
Perineal 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	
Periodontitis			
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	
Peritonitis			
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	
Peritonsillar 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	
Pneumonia			
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	
Pneumonia Bacterial			
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	
Pneumonia Necrotising			
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 Pneumococcal			

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	
Pneumonia Staphylococcal			
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	
Poliomyelitis			
subjects affected / exposed	1 / 6113 (0.02%)	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 Cellulitis			
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	
Post Procedural Infection			
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	
Post Procedural 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	
Post Procedural Sepsis			
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	
Postoperative Wound Infection			
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	
Prostatic 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	
Psoas Abscess			
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	
Pulmonary Sepsis			
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	
Pulmonary Tuberculosis			
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	
Pyelonephritis			
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	
Pyelonephritis Acute			
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	
Renal 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	
Respiratory Tract Infection			
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	
Scrotal Abscess			

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	
Sepsis			
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	
Septic Arthritis Staphylococcal			
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	
Septic Shock			
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	
Sinusitis 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	
Skin Bacterial Infection			
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	
Skin Infection			
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	
Soft Tissue Infection			
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	
Staphylococcal Bacteraemia			

subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Infection			
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	
Staphylococcal Osteomyelitis			
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	
Staphylococcal Sepsis			
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	
Subcutaneous Abscess			
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	
Tracheitis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
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	
Upper Respiratory Tract 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	
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	
Diabetic Ketoacidosis			
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	
Electrolyte Imbalance			
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	
Fluid Overload			
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	
Gout			
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	
Hyperamylasaemia			
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	
Hypercalcaemia			
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	
Hyperglycaemia			
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	
Hyperglycaemic Hyperosmolar Nonketotic Syndrome			

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	
Metabolic Acidosis			
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	
Obesity			
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	
Type 1 Diabetes Mellitus			
subjects affected / exposed	1 / 6113 (0.02%)	0 / 3057 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 Diabetes Mellitus			
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 %

Non-serious adverse events	C. Difficile Vaccine Group	Placebo Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1347 / 6113 (22.04%)	401 / 3057 (13.12%)	
Nervous system disorders			
Headache			
subjects affected / exposed	531 / 6113 (8.69%)	229 / 3057 (7.49%)	
occurrences (all)	758	327	
General disorders and administration site conditions			
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 ≥ 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 ≥ 72 to stays lasting ≥ 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: