



Clinical trial results:

A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy

Summary

EudraCT number	2013-004494-28
Trial protocol	GB CZ IT HU DE BG ES PL LT SK FR
Global end of trial date	30 October 2018

Results information

Result version number	v1 (current)
This version publication date	16 November 2019
First version publication date	16 November 2019

Trial information

Trial identification

Sponsor protocol code	28431754DNE3001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02065791
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 US Route 202, Raritan, NJ 08869, United States,
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.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	30 October 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 October 2018
Global end of trial reached?	Yes
Global end of trial date	30 October 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study was to assess the efficacy of canagliflozin relative to placebo in reducing the composite endpoint of doubling of serum creatinine, end-stage kidney disease (ESKD), and renal or cardiovascular (CV) death in subjects with type 2 diabetes mellitus (T2DM), Stage 2 or 3 chronic kidney disease (CKD) and macroalbuminuria who were receiving standard of care.

Protection of trial subjects:

Safety was evaluated throughout the study and included adverse events (AEs), hypoglycemic episodes, clinical safety laboratory tests (hematology, serum chemistry, urinalysis), and vital sign measurements (blood pressure and pulse rate).

Background therapy:

Standard of care including a maximum tolerated labeled daily dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB).

Evidence for comparator: -

Actual start date of recruitment	21 February 2014
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	United Arab Emirates: 1
Country: Number of subjects enrolled	Argentina: 426
Country: Number of subjects enrolled	Australia: 38
Country: Number of subjects enrolled	Bulgaria: 29
Country: Number of subjects enrolled	Brazil: 314
Country: Number of subjects enrolled	Canada: 172
Country: Number of subjects enrolled	Chile: 52
Country: Number of subjects enrolled	China: 129
Country: Number of subjects enrolled	Colombia: 94
Country: Number of subjects enrolled	Czech Republic: 57
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Spain: 141
Country: Number of subjects enrolled	France: 61
Country: Number of subjects enrolled	United Kingdom: 118
Country: Number of subjects enrolled	Guatemala: 55
Country: Number of subjects enrolled	Hungary: 135
Country: Number of subjects enrolled	India: 144

Country: Number of subjects enrolled	Italy: 90
Country: Number of subjects enrolled	Japan: 110
Country: Number of subjects enrolled	Korea, Republic of: 122
Country: Number of subjects enrolled	Lithuania: 7
Country: Number of subjects enrolled	Mexico: 303
Country: Number of subjects enrolled	Malaysia: 135
Country: Number of subjects enrolled	New Zealand: 61
Country: Number of subjects enrolled	Philippines: 71
Country: Number of subjects enrolled	Poland: 50
Country: Number of subjects enrolled	Romania: 59
Country: Number of subjects enrolled	Russian Federation: 133
Country: Number of subjects enrolled	Serbia: 40
Country: Number of subjects enrolled	Slovakia: 66
Country: Number of subjects enrolled	Taiwan: 37
Country: Number of subjects enrolled	Ukraine: 371
Country: Number of subjects enrolled	United States: 707
Country: Number of subjects enrolled	South Africa: 62
Worldwide total number of subjects	4401
EEA total number of subjects	824

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)	2344
From 65 to 84 years	2041
85 years and over	16

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 12,900 subjects were prescreened, of those, 8,932 were screened. A total of 4,401 subjects were randomized, with 2,199 and 2,202 subjects assigned to placebo and canagliflozin 100 mg, respectively.

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	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received matching placebo orally once daily.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Matching placebo tablet was administered orally once daily.

Arm title	Canagliflozin 100 mg
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Arm description:

Subjects received canagliflozin 100 milligram (mg) orally once daily.

Arm type	Experimental
Investigational medicinal product name	Canagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Canagliflozin 100 mg over-encapsulated tablet was administered orally once daily.

Number of subjects in period 1	Placebo	Canagliflozin 100 mg
Started	2199	2202
Treated	2197	2200
Completed	2174	2187
Not completed	25	15
Consent withdrawn by subject	11	5
Other - closed site	1	1
Lost to follow-up	13	9

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received matching placebo orally once daily.	
Reporting group title	Canagliflozin 100 mg
Reporting group description: Subjects received canagliflozin 100 milligram (mg) orally once daily.	

Reporting group values	Placebo	Canagliflozin 100 mg	Total
Number of subjects	2199	2202	4401
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1151	1193	2344
From 65 to 84 years	1038	1003	2041
85 years and over	10	6	16
Title for AgeContinuous Units: years			
arithmetic mean	63.2	62.9	
standard deviation	± 9.23	± 9.17	-
Title for Gender Units: subjects			
Female	732	762	1494
Male	1467	1440	2907

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received matching placebo orally once daily.	
Reporting group title	Canagliflozin 100 mg
Reporting group description: Subjects received canagliflozin 100 milligram (mg) orally once daily.	

Primary: Primary Composite Endpoint of Doubling of Serum Creatinine (DoSC), End-stage Kidney Disease (ESKD), and Renal or CV Death

End point title	Primary Composite Endpoint of Doubling of Serum Creatinine (DoSC), End-stage Kidney Disease (ESKD), and Renal or CV Death
End point description: Primary composite endpoint included composite of DoSC, ESKD, and renal/CV death. DoSC: from baseline average determination (sustained and confirmed by repeat central laboratory (CL) measure after at least 30 days and preferably within 60 days). ESKD: initiation of maintenance dialysis for at least 30 days, or renal transplantation, or estimated glomerular filtration rate (eGFR) value of less than (<)15 milliliters per minute per 1.73 square meters (mL/min/1.73 m ²) (sustained and confirmed by repeat CL measure after at least 30 days and preferably within 60 days). Renal death: death in subjects who reached ESKD, die without initiating renal replacement therapy, and no other cause of death was determined via adjudication. Adjudication of these events by Endpoint Adjudication Committee (EAC) was performed in a blinded fashion. Event rate estimated based on time to first occurrence of primary composite endpoint are presented. Intent-to-treat (ITT) population: all randomized subjects.	
End point type	Primary
End point timeframe: Up to 4.6 years	

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	61.24	43.21		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Canagliflozin 100 mg v Placebo

Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.82

Secondary: Composite Endpoint of CV Death and Hospitalized Heart Failure (HHF)

End point title	Composite Endpoint of CV Death and Hospitalized Heart Failure (HHF)
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End point description:

The composite endpoint included CV death and HHF. CV death included death due to myocardial infarction (MI), stroke, heart failure, sudden death, death during a CV procedure or as a result of procedure-related complications, or death due to other CV causes. For analytic purposes, undetermined causes of death were considered CV deaths. In determining whether a death event is CV in nature, the EAC took into consideration both the proximate and underlying causes. Adjudication of these events by the EAC was performed in a blinded fashion. Event rate estimated based on the time to the first occurrence of the composite endpoint of CV death and HHF are presented. The ITT population consisted of all randomized subjects.

End point type	Secondary
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End point timeframe:

Up to 4.6 years

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	45.44	31.47		

Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
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Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.83

Secondary: Major Adverse Cardiac Event (MACE)

End point title	Major Adverse Cardiac Event (MACE)
End point description:	
The composite endpoint included CV death, non-fatal MI, and non-fatal stroke (that is, 3-point MACE). Adjudication of these events by the EAC was performed in a blinded fashion. Event rate estimated based on the time to the first occurrence of MACE are presented. The ITT population consisted of all randomized subjects.	
End point type	Secondary
End point timeframe:	
Up to 4.6 years	

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	48.67	38.71		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0121
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.95

Secondary: Hospitalized Heart Failure (HHF)

End point title	Hospitalized Heart Failure (HHF)
End point description:	
Adjudication of these events by the Endpoint Adjudication Committee (EAC) was performed in a blinded fashion. Event rates estimated based on the time to the first occurrence of hospitalized heart failure were presented. The ITT population consisted of all randomized subjects.	
End point type	Secondary
End point timeframe:	
Up to 4.6 years	

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	25.33	15.65		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	0.8

Secondary: Renal Composite Endpoint

End point title	Renal Composite Endpoint
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End point description:

The renal composite endpoint included DoSC, ESKD, and renal death. DoSC: from baseline average determination (sustained and confirmed by repeat central laboratory measure after at least 30 days and preferably within 60 days). ESKD: initiation of maintenance dialysis for at least 30 days, or renal transplantation, or an eGFR value of $<15 \text{ mL/min/1.73 m}^2$ (sustained and confirmed by repeat central laboratory measure after at least 30 days and preferably within 60 days). Renal death: death in subjects who reached ESKD, die without initiating renal replacement therapy, and no other cause of death was determined via adjudication. Adjudication of these events by the EAC was performed in a blinded fashion. Event rate estimated based on the time to the first occurrence of the renal composite endpoint are presented. The ITT population consisted of all randomized subjects.

End point type	Secondary
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End point timeframe:

Up to 4.6 years

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	40.36	26.99		

Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.81

Secondary: Cardiovascular (CV) Death

End point title	Cardiovascular (CV) Death
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End point description:

CV death included death due to MI, stroke, heart failure, sudden death, death during a CV procedure or as a result of procedure-related complications, or death due to other CV causes. For analytic purposes, undetermined causes of death were considered CV deaths. In determining whether a death event is a CV in nature, the EAC took into consideration both the proximate and underlying causes. Adjudication of these events by the EAC was performed in a blinded fashion. Event rate estimated based on the time to the first occurrence of CV death are presented. The ITT population consisted of all randomized subjects.

End point type	Secondary
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End point timeframe:

Up to 4.6 years

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	24.38	19.01		

Statistical analyses

Statistical analysis title	Statistical Analysis
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0502
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1

Secondary: All-cause Mortality

End point title	All-cause Mortality
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End point description:

Adjudication of these events by Endpoint Adjudication Committee (EAC) was performed in a blinded fashion. Event rate estimated based on time to first occurrence of all-cause mortality are presented. ITT population consisted of all randomized subjects.

End point type	Secondary
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End point timeframe:

Up to 4.6 years

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	35.00	29.04		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0727
Method	Cox proportional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.02

Secondary: CV Composite Endpoint

End point title	CV Composite Endpoint
End point description:	
<p>The CV composite endpoint included CV death, non-fatal MI, non-fatal stroke, hospitalized heart failure, and hospitalized unstable angina. CV death included death due to MI, stroke, heart failure, sudden death, death during a CV procedure or as a result of procedure-related complications, or death due to other CV causes. For analytic purposes, undetermined causes of death were considered CV deaths. In determining whether a death event is a CV in nature, the EAC took into consideration both the proximate and underlying causes. Adjudication of these events by the EAC was performed in a blinded fashion. Event rate estimated based on the time to the first occurrence of the CV composite endpoint are presented. The ITT population consisted of all randomized subjects.</p>	
End point type	Secondary
End point timeframe:	
Up to 4.6 years	

End point values	Placebo	Canagliflozin 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2199	2202		
Units: Event rate per 1000 subject-years				
number (not applicable)	66.95	49.35		

Statistical analyses

Statistical analysis title	Statistical Analysis
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	4401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Cox proportional hazards
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.86

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 4.6 years

Adverse event reporting additional description:

Safety population included all randomized subjects who received at least 1 dose of study drug.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received matching placebo orally once daily.

Reporting group title	Canagliflozin 100 mg
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Reporting group description:

Subjects received canagliflozin 100 milligram (mg) orally once daily.

Serious adverse events	Placebo	Canagliflozin 100 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	806 / 2197 (36.69%)	737 / 2200 (33.50%)	
number of deaths (all causes)	193	164	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Leukaemia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma Gastric			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of Colon			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-Cell Lymphoma			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal Cell Carcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Neoplasm of Bladder			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	4 / 2197 (0.18%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Neoplasm			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Transitional Cell Carcinoma			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Cancer Metastatic			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cancer			

subjects affected / exposed	2 / 2197 (0.09%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
Colon Neoplasm			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diffuse Large B-Cell Lymphoma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Adenocarcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Cancer			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Neoplasm			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic Neoplasm			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular Carcinoma			
subjects affected / exposed	3 / 2197 (0.14%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Invasive Breast Carcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive Lobular Breast Carcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestine Benign Neoplasm			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Cancer			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Adenocarcinoma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung Cancer Metastatic			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Lung Neoplasm			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung Neoplasm Malignant			
subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant Melanoma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 Unknown Primary Site			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningioma Malignant			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to Bone			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to Liver			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic Renal Cell Carcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neuroendocrine Tumour			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's Lymphoma Stage Ii			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Adenocarcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal Squamous Cell Carcinoma			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Endometrioid Carcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Carcinoma			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic Carcinoma Metastatic			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pancreatic Neoplasm			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Papillary Thyroid Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal Carcinoma Metastatic			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pituitary Tumour Benign			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma Cell Myeloma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer			
subjects affected / exposed	4 / 2197 (0.18%)	8 / 2200 (0.36%)	
occurrences causally related to treatment / all	0 / 4	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Adenoma			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Adenocarcinoma			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Adenoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cell Carcinoma			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cell Carcinoma Stage I			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Neoplasm			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Oncocytoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary Gland Neoplasm			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma of Lung			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma of the Vulva			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue Neoplasm Malignant Stage Unspecified			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Transitional Cell Cancer of Renal Pelvis and Ureter Metastatic			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional Cell Cancer of the Renal Pelvis and Ureter			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional Cell Carcinoma			
subjects affected / exposed	0 / 2197 (0.00%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Uterine Cancer			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Leiomyoma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated Hypertension			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Aortic Dissection			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	5 / 2197 (0.23%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arterial Disorder			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Insufficiency			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory Collapse			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Deep Vein Thrombosis			
subjects affected / exposed	7 / 2197 (0.32%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Vascular Disorder			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism Arterial			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity Necrosis			
subjects affected / exposed	8 / 2197 (0.36%)	9 / 2200 (0.41%)	
occurrences causally related to treatment / all	1 / 9	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	7 / 2197 (0.32%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Crisis			
subjects affected / exposed	9 / 2197 (0.41%)	9 / 2200 (0.41%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive Emergency			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	3 / 2197 (0.14%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent Claudication			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche Syndrome			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrosis Ischaemic			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic Hypotension			
subjects affected / exposed	5 / 2197 (0.23%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	1 / 6	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	11 / 2197 (0.50%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Occlusion			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Ischaemia			
subjects affected / exposed	5 / 2197 (0.23%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral Vascular Disorder			

subjects affected / exposed	1 / 2197 (0.05%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 1	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Venous Disease			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock Haemorrhagic			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subclavian Artery Stenosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis Superficial			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Occlusion			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Haemorrhage			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous Thrombosis Limb			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained Products of Conception			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrophy			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Death			

subjects affected / exposed	1 / 2197 (0.05%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Chest Discomfort			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Pain			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication Associated with Device			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Critical Illness			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cyst			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	6 / 2197 (0.27%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 6	0 / 7	
Drowning			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait Disturbance			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised Oedema			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated Hernia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza Like Illness			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised Oedema			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Necrobiosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			

subjects affected / exposed	2 / 2197 (0.09%)	8 / 2200 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema Peripheral			
subjects affected / exposed	4 / 2197 (0.18%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Swelling			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Death			
subjects affected / exposed	8 / 2197 (0.36%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 8	0 / 3	
Sudden Cardiac Death			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Hypersensitivity			

subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired Phimosi			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomyosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Prostatic Hyperplasia			
subjects affected / exposed	4 / 2197 (0.18%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix Disorder			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile Dysfunction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital Swelling			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cyst			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Prolapse			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal Prolapse			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	8 / 2197 (0.36%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 11	1 / 6	
deaths causally related to treatment / all	0 / 1	1 / 3	
Acute Respiratory Distress Syndrome			

subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute Respiratory Failure			
subjects affected / exposed	6 / 2197 (0.27%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	
Apnoeic Attack			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	16 / 2197 (0.73%)	9 / 2200 (0.41%)	
occurrences causally related to treatment / all	0 / 22	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Respiratory Failure			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	3 / 2197 (0.14%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea at Rest			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Haematoma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nasal Polyps			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Septum Perforation			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian Syndrome			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	6 / 2197 (0.27%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic Pain			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pulmonary Arterial Hypertension			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Congestion			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
subjects affected / exposed	3 / 2197 (0.14%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 3	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pulmonary Fibrosis			
subjects affected / exposed	0 / 2197 (0.00%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Infarction			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary Mass			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	7 / 2197 (0.32%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Respiratory Depression			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Distress			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Failure			
subjects affected / exposed	10 / 2197 (0.46%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	0 / 12	1 / 11	
deaths causally related to treatment / all	0 / 3	1 / 4	
Sleep Apnoea Syndrome			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Leukoplakia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Affective Disorder			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed Suicide			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Confusional State			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental Status Changes			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance-Induced Psychotic Disorder			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide Attempt			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device Malfunction			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Bile Duct Obstruction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stone			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cholangitis Acute			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis Sclerosing			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	5 / 2197 (0.23%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	4 / 2197 (0.18%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Chronic			
subjects affected / exposed	1 / 2197 (0.05%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 2197 (0.09%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Cirrhosis			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic Function Abnormal			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Hepatitis			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Aspiration Bronchial			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Biopsy Kidney			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatinine Increased			
subjects affected / exposed	20 / 2197 (0.91%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 20	0 / 7	
deaths causally related to treatment / all	0 / 3	0 / 1	
Blood Glucose Increased			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood Osmolarity Decreased			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Urea Increased			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection Fraction Decreased			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular Filtration Rate Decreased			
subjects affected / exposed	1 / 2197 (0.05%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin Decreased			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin Increased			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight Decreased			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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			
Anaesthetic Complication			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	3 / 2197 (0.14%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Vertebral Fracture			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Injury			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Clavicle Fracture			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Reocclusion			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Vascular Graft Occlusion			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Expired Product Administered			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Neck Fracture			
subjects affected / exposed	2 / 2197 (0.09%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur Fracture			
subjects affected / exposed	1 / 2197 (0.05%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 1	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body in Eye			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture Displacement			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head Injury			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	5 / 2197 (0.23%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus Fracture			
subjects affected / exposed	2 / 2197 (0.09%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Dislocation			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Injury			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Rupture			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Sprain			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Injury			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus Injury			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Injury			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Strain			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella Fracture			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Haemorrhage			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Thrombosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Complication			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural Intestinal Perforation			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius Fracture			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road Traffic Accident			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Soft Tissue Injury			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Compression Fracture			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Subdural Haematoma			
subjects affected / exposed	3 / 2197 (0.14%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Subdural Haemorrhage			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Intracranial Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ulna Fracture			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Graft Occlusion			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	5 / 2197 (0.23%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Dehiscence			

subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist Fracture			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	8 / 2197 (0.36%)	12 / 2200 (0.55%)	
occurrences causally related to treatment / all	0 / 8	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute Left Ventricular Failure			
subjects affected / exposed	4 / 2197 (0.18%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Myocardial Infarction			
subjects affected / exposed	38 / 2197 (1.73%)	38 / 2200 (1.73%)	
occurrences causally related to treatment / all	1 / 40	1 / 42	
deaths causally related to treatment / all	0 / 10	0 / 7	
Angina Pectoris			
subjects affected / exposed	14 / 2197 (0.64%)	21 / 2200 (0.95%)	
occurrences causally related to treatment / all	0 / 14	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Unstable			
subjects affected / exposed	29 / 2197 (1.32%)	17 / 2200 (0.77%)	
occurrences causally related to treatment / all	0 / 33	2 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			

subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis Coronary Artery			
subjects affected / exposed	3 / 2197 (0.14%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Fibrillation			
subjects affected / exposed	19 / 2197 (0.86%)	16 / 2200 (0.73%)	
occurrences causally related to treatment / all	0 / 22	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial Flutter			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block Complete			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block First Degree			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brugada Syndrome			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	7 / 2197 (0.32%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 5	0 / 4	
Cardiac Asthma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Disorder			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure			
subjects affected / exposed	50 / 2197 (2.28%)	34 / 2200 (1.55%)	
occurrences causally related to treatment / all	1 / 54	1 / 43	
deaths causally related to treatment / all	0 / 4	0 / 2	
Cardiac Failure Acute			
subjects affected / exposed	6 / 2197 (0.27%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac Failure Chronic			
subjects affected / exposed	4 / 2197 (0.18%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure Congestive			
subjects affected / exposed	48 / 2197 (2.18%)	24 / 2200 (1.09%)	
occurrences causally related to treatment / all	0 / 59	2 / 27	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardiac Fibrillation			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Tamponade			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-Respiratory Arrest			
subjects affected / exposed	3 / 2197 (0.14%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 3	0 / 4	
Cardiogenic Shock			
subjects affected / exposed	8 / 2197 (0.36%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 6	0 / 2	
Cardiomyopathy			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal Syndrome			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Left Ventricular Failure			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Right Ventricular Failure			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cor Pulmonale			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Disease			
subjects affected / exposed	23 / 2197 (1.05%)	9 / 2200 (0.41%)	
occurrences causally related to treatment / all	1 / 27	1 / 9	
deaths causally related to treatment / all	0 / 3	0 / 0	
Coronary Artery Insufficiency			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Occlusion			
subjects affected / exposed	0 / 2197 (0.00%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Stenosis			
subjects affected / exposed	5 / 2197 (0.23%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Heart Disease			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic Cardiomyopathy			
subjects affected / exposed	6 / 2197 (0.27%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Left Ventricular Failure			
subjects affected / exposed	5 / 2197 (0.23%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral Valve Incompetence			

subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
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 / 2197 (1.23%)	22 / 2200 (1.00%)	
occurrences causally related to treatment / all	3 / 31	0 / 23	
deaths causally related to treatment / all	0 / 11	0 / 9	
Myocardial Ischaemia			
subjects affected / exposed	8 / 2197 (0.36%)	8 / 2200 (0.36%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocarditis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial Effusion			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless Electrical Activity			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right Ventricular Failure			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Node Dysfunction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid Valve Incompetence			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Arrhythmia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Extrasystoles			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Fibrillation			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Ventricular Tachycardia			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amputation Stump Pain			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar Migraine			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Injury			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain Oedema			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carotid Artery Occlusion			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Artery Stenosis			
subjects affected / exposed	8 / 2197 (0.36%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda Equina Syndrome			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar Haemorrhage			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebellar Infarction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar Stroke			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral Haematoma			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral Haemorrhage			
subjects affected / exposed	4 / 2197 (0.18%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral Hypoperfusion			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral Infarction			
subjects affected / exposed	7 / 2197 (0.32%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral Ischaemia			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular Accident			

subjects affected / exposed	36 / 2197 (1.64%)	30 / 2200 (1.36%)	
occurrences causally related to treatment / all	1 / 36	2 / 30	
deaths causally related to treatment / all	0 / 7	0 / 3	
Cervical Radiculopathy			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Inflammatory Demyelinating Polyradiculoneuropathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clonus			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed Level of Consciousness			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Autonomic Neuropathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Hyperosmolar Coma			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Neuropathy			

subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dural Arteriovenous Fistula			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolus Cerebral Infarction			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolus Stroke			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial Paralysis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised Tonic-Clonic Seizure			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage Intracranial			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Haemorrhagic Stroke			
subjects affected / exposed	4 / 2197 (0.18%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic Transformation Stroke			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Headache			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic Coma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (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	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial Mass			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic Cerebral Infarction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Neuropathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Stroke			
subjects affected / exposed	17 / 2197 (0.77%)	14 / 2200 (0.64%)	
occurrences causally related to treatment / all	0 / 18	0 / 14	
deaths causally related to treatment / all	0 / 3	0 / 0	
Lacunar Infarction			
subjects affected / exposed	4 / 2197 (0.18%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Language Disorder			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Radiculopathy			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral Radiculopathy			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's Disease			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Piriformis Syndrome			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Progressive Supranuclear Palsy			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	3 / 2197 (0.14%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension Headache			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic Infarction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	4 / 2197 (0.18%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Encephalopathy			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis Cerebral			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Artery Stenosis			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vith Nerve Paralysis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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	10 / 2197 (0.46%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Vitamin B12 Deficiency			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicytopenia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic Anaemia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron Deficiency Anaemia			

subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic Anaemia			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic Normocytic Anaemia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic Anaemia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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			
Vertigo			
subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Positional			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle Closure Glaucoma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	9 / 2197 (0.41%)	8 / 2200 (0.36%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Subcapsular			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Retinopathy			
subjects affected / exposed	4 / 2197 (0.18%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Haemorrhage			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid Ptosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Maculopathy			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular Age-Related Macular Degeneration			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic Ischaemic Neuropathy			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Detachment			
subjects affected / exposed	2 / 2197 (0.09%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhegmatogenous Retinal Detachment			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tractional Retinal Detachment			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision Blurred			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual Impairment			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Adhesions			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Fat Apron			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Incarcerated Hernia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Lower			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Haemorrhage			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Gastritis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis Ischaemic			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Gastroparesis			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	2 / 2197 (0.09%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum Intestinal			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum Intestinal Haemorrhagic			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			

subjects affected / exposed	3 / 2197 (0.14%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epulis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Faeces Discoloured			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Poisoning			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Ulcer			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 2197 (0.05%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Haemorrhage			

subjects affected / exposed	6 / 2197 (0.27%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Incarcerated Inguinal Hernia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia			
subjects affected / exposed	1 / 2197 (0.05%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	1 / 2197 (0.05%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal Perforation			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Large Intestine Polyp			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoplakia Oral			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive Pancreatitis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 2197 (0.00%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Acute			
subjects affected / exposed	3 / 2197 (0.14%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Polyp			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Haemorrhage			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subileus			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swollen Tongue			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 2197 (0.05%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	4 / 2197 (0.18%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot			
subjects affected / exposed	10 / 2197 (0.46%)	15 / 2200 (0.68%)	
occurrences causally related to treatment / all	0 / 11	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Ulcer			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Eruption			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic Angioedema			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic Ulcer			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Generalised			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Ulcer			
subjects affected / exposed	8 / 2197 (0.36%)	18 / 2200 (0.82%)	
occurrences causally related to treatment / all	1 / 8	1 / 18	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	50 / 2197 (2.28%)	41 / 2200 (1.86%)	
occurrences causally related to treatment / all	6 / 52	4 / 43	
deaths causally related to treatment / all	0 / 5	1 / 3	
Anuria			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Azotaemia			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Cyst			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus Urinary			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Kidney Disease			
subjects affected / exposed	12 / 2197 (0.55%)	12 / 2200 (0.55%)	
occurrences causally related to treatment / all	1 / 14	1 / 13	
deaths causally related to treatment / all	0 / 1	0 / 2	
Diabetic Nephropathy			
subjects affected / exposed	10 / 2197 (0.46%)	12 / 2200 (0.55%)	
occurrences causally related to treatment / all	0 / 11	2 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
End Stage Renal Disease			
subjects affected / exposed	23 / 2197 (1.05%)	16 / 2200 (0.73%)	
occurrences causally related to treatment / all	1 / 24	3 / 17	
deaths causally related to treatment / all	0 / 1	0 / 4	
Glomerulonephritis Chronic			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			

subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	4 / 2197 (0.18%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nephrotic Syndrome			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic Bladder			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Artery Stenosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Colic			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
subjects affected / exposed	9 / 2197 (0.41%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Renal Impairment			

subjects affected / exposed	7 / 2197 (0.32%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	1 / 7	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal Injury			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Tubular Necrosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress Urinary Incontinence			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Stenosis			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Obstruction			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			

subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Mass			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Spinal Stenosis			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Wall Haematoma			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty Arthritis			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Displacement			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	5 / 2197 (0.23%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Spinal Stenosis			
subjects affected / exposed	5 / 2197 (0.23%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular Weakness			

subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Pain			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic Arthropathy			
subjects affected / exposed	3 / 2197 (0.14%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis Deformans			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	11 / 2197 (0.50%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in Extremity			

subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Column Stenosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Disorder			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Symphysiolysis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Lupus Erythematosus			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger Finger			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Foraminal Stenosis			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal Abscess			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Sepsis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abscess Limb			
subjects affected / exposed	0 / 2197 (0.00%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Wall Abscess			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Hepatitis B			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis Perforated			
subjects affected / exposed	3 / 2197 (0.14%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous Fistula Site Infection			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Bacterial			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical Pneumonia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Pyelonephritis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Sepsis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	7 / 2197 (0.32%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis Viral			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter Colitis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	26 / 2197 (1.18%)	18 / 2200 (0.82%)	
occurrences causally related to treatment / all	1 / 28	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cellulitis Staphylococcal			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Sinusitis			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Colitis			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Infection			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue Fever			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot Infection			
subjects affected / exposed	4 / 2197 (0.18%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Gangrene			
subjects affected / exposed	2 / 2197 (0.09%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	2 / 2197 (0.09%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysentery			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear Infection			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis Infectious			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter Infection			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis Bacterial			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			

subjects affected / exposed	5 / 2197 (0.23%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Escherichia Sepsis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	15 / 2197 (0.68%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	3 / 20	0 / 11	
deaths causally related to treatment / all	2 / 2	0 / 0	
Gas Gangrene			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	19 / 2197 (0.86%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 21	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Bacterial			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Viral			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Bacterial Infection			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giardiasis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin Abscess			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus Infection			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Echinococcosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Skin Ulcer			
subjects affected / exposed	6 / 2197 (0.27%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 6	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection in An Immunocompromised Host			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infective Exacerbation of Chronic Obstructive Airways Disease			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 2197 (0.05%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Discitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis Fungal			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Abscess			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	6 / 2197 (0.27%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			

subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infection			
subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningitis Bacterial			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Necrotising Fasciitis			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Onychomycosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Opisthorchiasis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	11 / 2197 (0.50%)	11 / 2200 (0.50%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis Acute			
subjects affected / exposed	0 / 2197 (0.00%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis Chronic			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal Abscess			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal Abscess			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	86 / 2197 (3.91%)	63 / 2200 (2.86%)	
occurrences causally related to treatment / all	1 / 104	1 / 72	
deaths causally related to treatment / all	0 / 15	1 / 13	
Pneumonia Bacterial			

subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Influenzal			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Staphylococcal			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Streptococcal			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Viral			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Infection			
subjects affected / exposed	3 / 2197 (0.14%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas Bronchitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Sepsis			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	5 / 2197 (0.23%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	3 / 5	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Acute			
subjects affected / exposed	2 / 2197 (0.09%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	1 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Chronic			
subjects affected / exposed	2 / 2197 (0.09%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Abscess			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal Abscess			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrub Typhus			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	12 / 2197 (0.55%)	11 / 2200 (0.50%)	
occurrences causally related to treatment / all	0 / 13	0 / 11	
deaths causally related to treatment / all	0 / 4	0 / 2	
Septic Shock			
subjects affected / exposed	12 / 2197 (0.55%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 12	0 / 5	
deaths causally related to treatment / all	0 / 6	0 / 5	
Soft Tissue Infection			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Bacteraemia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Sepsis			

subjects affected / exposed	2 / 2197 (0.09%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal Infection			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous Abscess			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth Abscess			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 2197 (0.14%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	21 / 2197 (0.96%)	25 / 2200 (1.14%)	
occurrences causally related to treatment / all	9 / 25	12 / 30	
deaths causally related to treatment / all	0 / 0	0 / 2	
Urinary Tract Infection Fungal			

subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	3 / 2197 (0.14%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	2 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Viral Infection			
subjects affected / exposed	1 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (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	1 / 2197 (0.05%)	6 / 2200 (0.27%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	8 / 2197 (0.36%)	4 / 2200 (0.18%)	
occurrences causally related to treatment / all	1 / 8	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Diabetes Mellitus			
subjects affected / exposed	10 / 2197 (0.46%)	5 / 2200 (0.23%)	
occurrences causally related to treatment / all	0 / 12	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Inadequate Control			

subjects affected / exposed	12 / 2197 (0.55%)	7 / 2200 (0.32%)	
occurrences causally related to treatment / all	0 / 14	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic Ketoacidosis			
subjects affected / exposed	2 / 2197 (0.09%)	9 / 2200 (0.41%)	
occurrences causally related to treatment / all	0 / 2	2 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic Ketosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic Metabolic Decompensation			
subjects affected / exposed	3 / 2197 (0.14%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte Imbalance			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid Overload			
subjects affected / exposed	4 / 2197 (0.18%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid Retention			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
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 / 2197 (0.05%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			

subjects affected / exposed	11 / 2197 (0.50%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 11	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic Hyperosmolar Nonketotic Syndrome			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	10 / 2197 (0.46%)	10 / 2200 (0.45%)	
occurrences causally related to treatment / all	0 / 10	4 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperlipidaemia			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	11 / 2197 (0.50%)	17 / 2200 (0.77%)	
occurrences causally related to treatment / all	3 / 11	6 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	3 / 2197 (0.14%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 2197 (0.18%)	3 / 2200 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypophagia			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoproteinaemia			

subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic Acidosis			
subjects affected / exposed	0 / 2197 (0.00%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic Acidosis			
subjects affected / exposed	6 / 2197 (0.27%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	1 / 6	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metabolic Disorder			
subjects affected / exposed	1 / 2197 (0.05%)	0 / 2200 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	1 / 2197 (0.05%)	2 / 2200 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 Diabetes Mellitus			
subjects affected / exposed	2 / 2197 (0.09%)	1 / 2200 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Placebo	Canagliflozin 100 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1447 / 2197 (65.86%)	1320 / 2200 (60.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	193 / 2197 (8.78%)	144 / 2200 (6.55%)	
occurrences (all)	313	196	
Hypotension			
subjects affected / exposed	30 / 2197 (1.37%)	57 / 2200 (2.59%)	
occurrences (all)	31	71	
General disorders and administration site conditions			
Oedema Peripheral			
subjects affected / exposed	199 / 2197 (9.06%)	119 / 2200 (5.41%)	
occurrences (all)	235	135	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	81 / 2197 (3.69%)	80 / 2200 (3.64%)	
occurrences (all)	93	94	
Dyspnoea			
subjects affected / exposed	46 / 2197 (2.09%)	35 / 2200 (1.59%)	
occurrences (all)	49	38	
Investigations			
Blood Creatinine Increased			
subjects affected / exposed	185 / 2197 (8.42%)	140 / 2200 (6.36%)	
occurrences (all)	205	152	
Glomerular Filtration Rate Decreased			
subjects affected / exposed	80 / 2197 (3.64%)	63 / 2200 (2.86%)	
occurrences (all)	85	63	
Injury, poisoning and procedural complications			
Limb Injury			
subjects affected / exposed	45 / 2197 (2.05%)	43 / 2200 (1.95%)	
occurrences (all)	47	46	
Nervous system disorders			
Diabetic Neuropathy			
subjects affected / exposed	69 / 2197 (3.14%)	56 / 2200 (2.55%)	
occurrences (all)	74	57	

Headache subjects affected / exposed occurrences (all)	65 / 2197 (2.96%) 82	69 / 2200 (3.14%) 81	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	136 / 2197 (6.19%) 144	77 / 2200 (3.50%) 81	
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	50 / 2197 (2.28%) 54	46 / 2200 (2.09%) 50	
Eye disorders Cataract subjects affected / exposed occurrences (all) Diabetic Retinopathy subjects affected / exposed occurrences (all)	80 / 2197 (3.64%) 94 55 / 2197 (2.50%) 56	58 / 2200 (2.64%) 65 65 / 2200 (2.95%) 74	
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	82 / 2197 (3.73%) 93 105 / 2197 (4.78%) 120 52 / 2197 (2.37%) 62 48 / 2197 (2.18%) 55	80 / 2200 (3.64%) 91 91 / 2200 (4.14%) 100 54 / 2200 (2.45%) 58 41 / 2200 (1.86%) 43	
Skin and subcutaneous tissue disorders Skin Ulcer subjects affected / exposed occurrences (all)	70 / 2197 (3.19%) 89	85 / 2200 (3.86%) 103	
Renal and urinary disorders			

Acute Kidney Injury subjects affected / exposed occurrences (all)	51 / 2197 (2.32%) 63	50 / 2200 (2.27%) 56	
Renal Impairment subjects affected / exposed occurrences (all)	61 / 2197 (2.78%) 64	42 / 2200 (1.91%) 45	
End Stage Renal Disease subjects affected / exposed occurrences (all)	52 / 2197 (2.37%) 57	30 / 2200 (1.36%) 32	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	83 / 2197 (3.78%) 90	81 / 2200 (3.68%) 87	
Back Pain subjects affected / exposed occurrences (all)	99 / 2197 (4.51%) 113	94 / 2200 (4.27%) 105	
Pain in Extremity subjects affected / exposed occurrences (all)	54 / 2197 (2.46%) 61	56 / 2200 (2.55%) 63	
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	86 / 2197 (3.91%) 96	83 / 2200 (3.77%) 104	
Gastroenteritis subjects affected / exposed occurrences (all)	51 / 2197 (2.32%) 53	49 / 2200 (2.23%) 52	
Influenza subjects affected / exposed occurrences (all)	88 / 2197 (4.01%) 105	87 / 2200 (3.95%) 93	
Nasopharyngitis subjects affected / exposed occurrences (all)	133 / 2197 (6.05%) 180	130 / 2200 (5.91%) 184	
Onychomycosis subjects affected / exposed occurrences (all)	33 / 2197 (1.50%) 33	45 / 2200 (2.05%) 46	
Pneumonia			

subjects affected / exposed	52 / 2197 (2.37%)	41 / 2200 (1.86%)	
occurrences (all)	61	42	
Respiratory Tract Infection			
subjects affected / exposed	44 / 2197 (2.00%)	19 / 2200 (0.86%)	
occurrences (all)	63	22	
Upper Respiratory Tract Infection			
subjects affected / exposed	117 / 2197 (5.33%)	90 / 2200 (4.09%)	
occurrences (all)	141	109	
Urinary Tract Infection			
subjects affected / exposed	185 / 2197 (8.42%)	202 / 2200 (9.18%)	
occurrences (all)	271	280	
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	44 / 2197 (2.00%)	24 / 2200 (1.09%)	
occurrences (all)	52	26	
Hyperglycaemia			
subjects affected / exposed	74 / 2197 (3.37%)	54 / 2200 (2.45%)	
occurrences (all)	81	67	
Hyperkalaemia			
subjects affected / exposed	152 / 2197 (6.92%)	129 / 2200 (5.86%)	
occurrences (all)	206	153	
Hyperuricaemia			
subjects affected / exposed	75 / 2197 (3.41%)	64 / 2200 (2.91%)	
occurrences (all)	83	70	
Hypoglycaemia			
subjects affected / exposed	227 / 2197 (10.33%)	213 / 2200 (9.68%)	
occurrences (all)	1128	957	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 June 2014	The primary reason for Amendment INT-1 was to reflect recommendations from the US Food and Drug Administration (FDA) for this study.
03 February 2015	The primary reason for Amendment INT-2 was to revise inclusion criteria to allow subjects with higher baseline HbA1c values who may have benefited from the study treatment to participate in the study.
29 September 2015	The primary reason for Amendment INT-3 was to inform investigators of additional safety reporting requirements associated with DKA, which was identified as an adverse event of special interest.
29 January 2016	The primary reason for Amendment INT-4 was to expand the sample size from 3,700 to 4,200 subjects to increase the likelihood of accruing endpoints within the primary composite.
06 May 2016	The primary reason for Amendment INT-5 was to add new safety information and guidance regarding subject management surrounding the event of lower-extremity amputation.
06 September 2017	The primary reason for Amendment INT-6 was to decrease the number of primary composite events required for the interim analysis from 540 to 405, based on internal and external data of the effects of SGLT2 inhibitors on renal endpoints indicating that the beneficial effects of canagliflozin on renal outcomes may be detected with fewer events in the primary composite endpoint.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported