Clinical trial results:
A Randomized, Double-blind, Event-driven, Multicenter Study Comparing the Efficacy and Safety of Rivaroxaban with Placebo for Reducing the Risk of Death, Myocardial Infarction or Stroke in Subjects with Heart Failure and Significant Coronary Artery Disease Following an Episode of Decompensated Heart Failure

Summary

EudraCT number	2013-000046-19
Trial protocol	ES CZ DE NL BG PL HU SE IT GB EE LT PT DK LV SK GR
Global end of trial date	02 May 2018

Results information

Result version number	v1 (current)
This version publication date	04 May 2019
First version publication date	04 May 2019

Trial information

Trial identification

Sponsor protocol code	RIVAROXHFA3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01877915
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920, Route 202 South, Raritan, NJ, United States, 08869
Public contact	Clinical Registry group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen-Cilag International NV, 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	02 May 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate that rivaroxaban was superior to placebo in subjects with heart failure (HF) and significant coronary artery disease (CAD), who were receiving standard care, in reducing the risk of the composite of all-cause mortality (ACM), myocardial infarction (MI), or stroke following an index event.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices (GCP) and applicable regulatory requirements. Safety was assessed by the evaluation of the principal safety outcome, other bleeding outcomes, Adverse Events and laboratory evaluations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 September 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 152
Country: Number of subjects enrolled	Australia: 14
Country: Number of subjects enrolled	Bulgaria: 628
Country: Number of subjects enrolled	Brazil: 160
Country: Number of subjects enrolled	Canada: 28
Country: Number of subjects enrolled	China: 372
Country: Number of subjects enrolled	Czech Republic: 69
Country: Number of subjects enrolled	Germany: 64
Country: Number of subjects enrolled	Denmark: 18
Country: Number of subjects enrolled	Spain: 178
Country: Number of subjects enrolled	France: 20
Country: Number of subjects enrolled	United Kingdom: 25
Country: Number of subjects enrolled	Greece: 16
Country: Number of subjects enrolled	Hungary: 138
Country: Number of subjects enrolled	Italy: 71
Country: Number of subjects enrolled	Japan: 265
Country: Number of subjects enrolled	Korea, Republic of: 48
Country: Number of subjects enrolled	Lithuania: 35

Country: Number of subjects enrolled	Latvia: 25
Country: Number of subjects enrolled	Mexico: 146
Country: Number of subjects enrolled	Malaysia: 34
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Poland: 578
Country: Number of subjects enrolled	Portugal: 42
Country: Number of subjects enrolled	Romania: 398
Country: Number of subjects enrolled	Russian Federation: 550
Country: Number of subjects enrolled	Slovakia: 82
Country: Number of subjects enrolled	Sweden: 5
Country: Number of subjects enrolled	Turkey: 192
Country: Number of subjects enrolled	Ukraine: 529
Country: Number of subjects enrolled	United States: 121
Country: Number of subjects enrolled	South Africa: 16
Worldwide total number of subjects	5022
EEA total number of subjects	2395

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)	2159
From 65 to 84 years	2709
85 years and over	154

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 5,667 subjects were screened for eligibility and 5,022 subjects were randomly assigned into 1 of the 2 treatment groups: rivaroxaban (N= 2,507) or matching placebo (N=2,515).

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	Rivaroxaban

Arm description:

Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

Arm type	Experimental
Investigational medicinal product name	Rivaroxaban 2.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 2.5 mg of rivaroxaban tablet orally twice daily.

Arm title	Placebo

Arm description:

Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

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:

Subjects received matching placebo orally twice daily.

Number of subjects in period 1	Rivaroxaban	Placebo
Started	2507	2515
Completed	2453	2447
Not completed	54	68
Consent withdrawn by subject	42	55
Other	2	4
Lost to follow-up	10	9

Baseline characteristics

Reporting groups	
Reporting group title	Rivaroxaban
Reporting group description:	
Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).	
Reporting group title	Placebo
Reporting group description:	
Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).	

Reporting group values	Rivaroxaban	Placebo	Total
Number of subjects	2507	2515	5022
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1061	1098	2159
From 65 to 84 years	1379	1330	2709
85 years and over	67	87	154
Title for AgeContinuous Units: years			
arithmetic mean	66.5	66.3	
standard deviation	± 10.07	± 10.27	-
Title for Gender Units: subjects			
Female	551	599	1150
Male	1956	1916	3872

End points

End points reporting groups

Reporting group title	Rivaroxaban
Reporting group description:	
Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).	
Reporting group title	Placebo
Reporting group description:	
Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).	

Primary: Event Rate of All-Cause Mortality, Myocardial Infarction (MI), or Stroke

End point title	Event Rate of All-Cause Mortality, Myocardial Infarction (MI), or Stroke
End point description:	
Event rate of all-cause mortality (ACM), MI, or stroke were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. Intent-to-Treat (ITT) analysis set included all randomized unique subjects who signed a valid informed consent. Subjects were analyzed according to the treatment group assigned, irrespective of the actual treatment received.	
End point type	Primary
End point timeframe:	
Up to Global treatment end date (approximately 54 months)	

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2507	2515		
Units: Event rate per 100 patient-year				
number (not applicable)	13.44	14.27		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban v Placebo
Number of subjects included in analysis	5022
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.05

Primary: Event Rate of Either Fatal Bleeding or Bleeding into a Critical Space with Potential for Permanent Disability

End point title	Event Rate of Either Fatal Bleeding or Bleeding into a Critical Space with Potential for Permanent Disability

End point description:

Event rate of either fatal bleeding or bleeding into critical space with potential for permanent disability were assessed. Fatal bleeding event was death within 7 days after bleeding event which required hospitalization or met ISTH major bleeding definition criteria. Fatal bleeding event included that met criteria in 3 1:Any ISTH major bleeding event considered to be primary cause of death by investigator; 2: ISTH major bleeding event not considered primary cause of death by investigator but resulted in death within 7 days;3: Any bleeding event resulted in hospital and death within 7 days. Bleeding with potential for permanent disability included 7 critical spaces: intracranial, intraspinal, intraocular. Event rate based on time to first occurrence of event were reported in the study. Event Rate/(100 pt-yr=100*n/(total risk exposure), where n is number of events. SAS: subjects who received at least one dose of study drug. 'N':number of subjects evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Up to 227 Weeks

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2499	2509		
Units: Event rate per 100 patient-year				
number (not applicable)				
Fatal Bleeding	0.22	0.22		
Critical Space Bleeding with Permanent Disability	0.32	0.48		

Statistical analyses

Statistical analysis title	Statistical Analysis 1 (Fatal Bleeding)
Comparison groups	Rivaroxaban v Placebo
Number of subjects included in analysis	5008
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.951
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	2.59

Statistical analysis title	Statistical Analysis 2 (Permanent Disability)
Comparison groups	Rivaroxaban v Placebo
Number of subjects included in analysis	5008
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.253
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.34

Secondary: Event Rate of Cardio Vascular Death or Re-Hospitalization for Worsening of Heart Failure (RHHF)

End point title	Event Rate of Cardio Vascular Death or Re-Hospitalization for Worsening of Heart Failure (RHHF)

End point description:

Event rate of cardio vascular (CV) death or re-hospitalization for worsening of heart failure were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

End point type	Secondary

End point timeframe:

Up to Global treatment end date (approximately 54 months)

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2507	2515		
Units: Event rate per 100 patient-year				
number (not applicable)	23.32	23.46		

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Cardio Vascular Death

End point title	Event Rate of Cardio Vascular Death

End point description:

Event rate of cardio vascular death were assessed. CV death included deaths due to spontaneous bleeding, MI, stroke, worsening HF and arrhythmias, death due to CV procedures and sudden death. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. IIT analysis set included all randomized unique subjects signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

End point type	Secondary

End point timeframe:

Up to Global treatment end date (approximately 54 months)

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2507	2515		
Units: Event rate per 100 patient-year				
number (not applicable)	9.46	9.96		

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Re-Hospitalization for Worsening of Heart Failure

End point title	Event Rate of Re-Hospitalization for Worsening of Heart Failure

End point description:

Event rate of re-hospitalization for worsening of heart failure were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

End point type	Secondary

End point timeframe:

Up to Global treatment end date (approximately 54 months)

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2507	2515		
Units: Event rate per 100 patient-year				
number (not applicable)	17.24	17.45		

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Re-Hospitalization for Cardio Vascular Events (RHCV)

End point title	Event Rate of Re-Hospitalization for Cardio Vascular Events (RHCV)

End point description:

Event rate of RHCV were assessed. Hospitalization for a CV event required that participants be hospitalized (in-patient or emergency department) for greater than 24 hours and must have met the following criterion:Discharge summary with primary reason for admission listed as CV in nature (eg, bleeding, arrhythmia, ACS, MI) other than HF which was captured in HF re-hospitalization. Event rate estimated based on time to first occurrence of the event were reported in study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

End point type	Secondary

End point timeframe:

Up to Global treatment end date (approximately 54 months)

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2507	2515		
Units: Event rate per 100 patient-year				
number (not applicable)	13.30	14.04		

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of all-Cause Mortality (ACM) or Re-Hospitalization for Worsening Heart Failure

End point title	Event Rate of all-Cause Mortality (ACM) or Re-Hospitalization for Worsening Heart Failure

End point description:

Event rate of all-cause mortality (ACM) or re-hospitalization for worsening heart failure were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

End point type	Secondary

End point timeframe:

Up to Global treatment end date (approximately 54 months)

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2507	2515		
Units: Event rate per 100 patient-year				
number (not applicable)	24.84	24.57		

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Bleeding Events that Requiring Hospitalization

End point title	Event Rate of Bleeding Events that Requiring Hospitalization

End point description:

Event rate of bleeding events and required Hospitalization were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. Safety Analysis Set (SAS) included all intent-to-treat subjects who received at least one dose of study drug. Here 'N' signifies number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 227 Weeks

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2499	2509		
Units: Event rate per 100 patient-year				
number (not applicable)	1.52	1.16		

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of International Society on Thrombosis and Haemostasis (ISTH) Major Bleeding Event

End point title	Event Rate of International Society on Thrombosis and Haemostasis (ISTH) Major Bleeding Event

End point description:

Event rate of ISTH major bleeding event were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = 100*n/(total risk exposure), where n is the number of events. Safety Analysis Set included all intent-to-treat subjects who received at least one dose of study drug. Here 'N' signifies number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 227 Weeks

End point values	Rivaroxaban	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2499	2509		
Units: Event rate per 100 patient-year				
number (not applicable)	2.04	1.21		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 54 Months

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Rivaroxaban

Reporting group description:

Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

Reporting group title	Placebo

Reporting group description:

Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

Serious adverse events	Rivaroxaban	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	479 / 2507 (19.11%)	451 / 2515 (17.93%)	
number of deaths (all causes)	565	571	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of Colon			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Cancer			
subjects affected / exposed	6 / 2507 (0.24%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bladder Cancer Recurrent			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain Neoplasm			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cancer Stage Ii			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Neoplasm			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Bronchial Carcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cervix Carcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear Cell Renal Cell Carcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Colon Cancer			

subjects affected / exposed	7 / 2507 (0.28%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	2 / 2	1 / 1	
Colon Cancer Metastatic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Colon Cancer Recurrent			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Neoplasm			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal Adenocarcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal Cancer			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear Neoplasm Malignant			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial Cancer Metastatic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Epiglottic Carcinoma			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Cancer			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Gastric Cancer			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Cancer Recurrent			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Cancer			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic Cancer			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Cancer Stage Iv			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hypopharyngeal Cancer			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Intestinal Adenocarcinoma			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Adenocarcinoma			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lung Cancer Metastatic			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	1 / 1	1 / 1	
Lung Carcinoma Cell Type Unspecified Stage Ii			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Lung Neoplasm			
subjects affected / exposed	1 / 2507 (0.04%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lung Neoplasm Malignant			
subjects affected / exposed	7 / 2507 (0.28%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 7	1 / 7	
deaths causally related to treatment / all	5 / 5	1 / 1	
Lymphoma			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Malignant Melanoma			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Neoplasm of Unknown Primary Site			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Meningioma			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to Central Nervous System			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Metastases to Liver			
subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Metastases to Lung			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic Neoplasm			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Metastatic Renal Cell Carcinoma			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Monoclonal Gammopathy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm Malignant			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Neoplasm of Orbit			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's Lymphoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal Squamous Cell Carcinoma			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pancreatic Carcinoma Metastatic			

subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Plasma Cell Myeloma			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Prostate Cancer			
subjects affected / exposed	4 / 2507 (0.16%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	1 / 1	
Prostate Cancer Metastatic			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer Stage Iv			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic Adenoma			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Adenocarcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Cancer Stage Iii			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Rectal Neoplasm			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Cancer			
subjects affected / exposed	2 / 2507 (0.08%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Renal Cancer Metastatic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Neoplasm			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Cell Carcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestine Carcinoma			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Testis Cancer			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat Cancer			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid Cancer			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Tongue Neoplasm			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional Cell Carcinoma			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Dissection			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Haemorrhage			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Arteriosclerosis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory Collapse			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Cryoglobulinaemia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Vascular Disorder			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity Necrosis			
subjects affected / exposed	3 / 2507 (0.12%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hypertension			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	4 / 2507 (0.16%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic Shock			

subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic Hypotension			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Ischaemia			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Vascular Disorder			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis Superficial			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian Artery Stenosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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			
Anal Sphincterotomy			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stent Removal			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Tumour Excision			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Operation			
subjects affected / exposed	3 / 2507 (0.12%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemotherapy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst Removal			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Debridement			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Management			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Therapy			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia Repair			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileostomy			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia Repair			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insertion of Ambulatory Peritoneal Catheter			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leg Amputation			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Bypass			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic Vessel Implantation			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Removal of Ambulatory Peritoneal Catheter			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Fusion Surgery			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Laminectomy			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral Prostatectomy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	5 / 2507 (0.20%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	2 / 5	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chest Discomfort			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Pain			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	3 / 3	
Disuse Syndrome			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Drug Withdrawal Syndrome			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Heteroplasia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia Malignant			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired Healing			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	5 / 2507 (0.20%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	5 / 5	3 / 3	
Non-Cardiac Chest Pain			

subjects affected / exposed	7 / 2507 (0.28%)	6 / 2515 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	4 / 2507 (0.16%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Inflammation			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Death			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cystocele			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cyst Torsion			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Polyp			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Respiratory Failure			
subjects affected / exposed	2 / 2507 (0.08%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Asthma			
subjects affected / exposed	5 / 2507 (0.20%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	

Atelectasis			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis Chronic			
subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	15 / 2507 (0.60%)	16 / 2515 (0.64%)	
occurrences causally related to treatment / all	0 / 18	0 / 21	
deaths causally related to treatment / all	1 / 1	1 / 1	
Cough			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	4 / 2507 (0.16%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea Paroxysmal Nocturnal			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial Lung Disease			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Disorder			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infiltration			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising Bronchiolitis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pleural Effusion			
subjects affected / exposed	3 / 2507 (0.12%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Aspiration			

subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Pneumothorax			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Fibrosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Hypertension			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Mass			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Oedema			
subjects affected / exposed	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Arrest			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Respiratory Failure			
subjects affected / exposed	9 / 2507 (0.36%)	5 / 2515 (0.20%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	4 / 4	3 / 3	
Respiratory Tract Inflammation			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal Cord Thickening			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol Abuse			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Withdrawal Syndrome			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Antisocial Personality Disorder			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety Disorder			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional State			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Illness Anxiety Disorder			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major Depression			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic Disorder Due to A General Medical Condition			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Self-Injurious Ideation			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Ideation			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device Dislocation			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute Hepatic Failure			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Colic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary Dilatation			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Cirrhosis			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	3 / 2507 (0.12%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cholangitis Acute			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cholecystitis			
subjects affected / exposed	10 / 2507 (0.40%)	5 / 2515 (0.20%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	1 / 2507 (0.04%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Chronic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 2507 (0.08%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis Alcoholic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic Cirrhosis			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Failure			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic Function Abnormal			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Lesion			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis Acute			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal Failure			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Jaundice			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Disorder			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal Hypertension			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Biopsy Pleura			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy Prostate			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatinine Increased			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Glucose Abnormal			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Glucose Fluctuation			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Enzyme Increased			
subjects affected / exposed	3 / 2507 (0.12%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Function Test Increased			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagogastroduodenoscopy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet Count Decreased			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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			
Accidental Overdose			
subjects affected / exposed	2 / 2507 (0.08%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol Poisoning			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Ankle Fracture			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Fissure			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns Third Degree			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Vertebral Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Contusion			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Fall			
subjects affected / exposed	5 / 2507 (0.20%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Femoral Neck Fracture			
subjects affected / exposed	1 / 2507 (0.04%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur Fracture			
subjects affected / exposed	8 / 2507 (0.32%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun Shot Wound			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hand Fracture			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hip Fracture			
subjects affected / exposed	6 / 2507 (0.24%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional Overdose			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Injury			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Limb Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Fractures			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella Fracture			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax Traumatic			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Complication			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Renal Failure			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Complication			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation Pneumonitis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib Fracture			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road Traffic Accident			

subjects affected / exposed	3 / 2507 (0.12%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	1 / 1	1 / 1	
Spinal Compression Fracture			
subjects affected / exposed	2 / 2507 (0.08%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Rupture			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal Burn			
subjects affected / exposed	2 / 2507 (0.08%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna Fracture			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Dehiscence			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous Malformation			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Buried Penis Syndrome			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Ventricular Thrombosis			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic Shock			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal Syndrome			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Palpitations			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amyotrophic Lateral Sclerosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Brain Injury			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Brain Oedema			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Neuropathy			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness Postural			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemianopia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic Coma			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-Ischaemic Encephalopathy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Intercostal Neuralgia			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Neuropathy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of Consciousness			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral Radiculopathy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroglycopenia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy Peripheral			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	6 / 2507 (0.24%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient Ischaemic Attack			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar Insufficiency			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 2507 (0.48%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	4 / 13	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Vitamin B12 Deficiency			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplastic Anaemia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron Deficiency Anaemia			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Positional			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	7 / 2507 (0.28%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract Nuclear			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular Hole			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmoplegia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy Hypertensive			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subretinal Fibrosis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual Acuity Reduced			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	6 / 2507 (0.24%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Tenderness			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Fissure			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	3 / 2507 (0.12%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac Disease			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental Caries			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	4 / 2507 (0.16%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Diverticulum Intestinal			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Obstruction			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 2507 (0.08%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive Duodenitis			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Poisoning			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	1 / 2507 (0.04%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	2 / 2507 (0.08%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis Erosive			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Angiodysplasia			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Disorder			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Necrosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Reflux Disease			

subjects affected / exposed	3 / 2507 (0.12%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Sphincter Insufficiency			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial Eventration			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus Paralytic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Incarcerated Inguinal Hernia			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated Umbilical Hernia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia			

subjects affected / exposed	7 / 2507 (0.28%)	9 / 2515 (0.36%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Infarction			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	5 / 2507 (0.20%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Enteritis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestinal Obstruction			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Large Intestine Polyp			
subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Disorder			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Necrosis			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Acute			
subjects affected / exposed	3 / 2507 (0.12%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Chronic			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative Gastritis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus of Small Bowel			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	3 / 2507 (0.12%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus Ulcer			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot			
subjects affected / exposed	6 / 2507 (0.24%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyshidrotic Eczema			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity Vasculitis			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrobiosis Lipoidica Diabeticorum			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Generalised			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Macular			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Lesion			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic Epidermal Necrolysis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	17 / 2507 (0.68%)	28 / 2515 (1.11%)	
occurrences causally related to treatment / all	0 / 19	0 / 33	
deaths causally related to treatment / all	3 / 3	2 / 2	
Calculus Urinary			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Kidney Disease			
subjects affected / exposed	14 / 2507 (0.56%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 16	0 / 7	
deaths causally related to treatment / all	1 / 1	0 / 0	
Diabetic Nephropathy			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End Stage Renal Disease			

subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iga Nephropathy			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	3 / 2507 (0.12%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy Toxic			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic Syndrome			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal Failure			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Artery Stenosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
subjects affected / exposed	12 / 2507 (0.48%)	12 / 2515 (0.48%)	
occurrences causally related to treatment / all	1 / 14	0 / 13	
deaths causally related to treatment / all	2 / 2	3 / 3	
Renal Impairment			
subjects affected / exposed	4 / 2507 (0.16%)	9 / 2515 (0.36%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Stenosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	3 / 2507 (0.12%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Disorder			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Obstruction			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Basedow's Disease			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Deformity			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty Arthritis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Degeneration			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Disorder			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Protrusion			
subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Spasms			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular Weakness			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in Extremity			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia Rheumatica			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid Arthritis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Osteoarthritis			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Pain			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal Abscess			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Limb			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Soft Tissue			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Abscess			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	3 / 2507 (0.12%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis Bacterial			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Infection			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Sepsis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			

subjects affected / exposed	12 / 2507 (0.48%)	9 / 2515 (0.36%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis Bacterial			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis Infective			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	7 / 2507 (0.28%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis Gangrenous			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cholecystitis Infective			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Tonsillitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Colitis			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Infection			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue Fever			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Related Infection			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot Infection			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Gangrene			
subjects affected / exposed	1 / 2507 (0.04%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Douglas' Abscess			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis Infectious			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter Infection			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Bacteraemia			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Infection			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Pyelonephritis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Sepsis			
subjects affected / exposed	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	7 / 2507 (0.28%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	2 / 2	0 / 0	
Gastritis Viral			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	6 / 2507 (0.24%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Shigella			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Pneumonia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hepatitis E			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Zoster Infection Neurological			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected Dermal Cyst			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Spondylitis			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	7 / 2507 (0.28%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Intervertebral Discitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	3 / 2507 (0.12%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Abscess			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infection			
subjects affected / exposed	8 / 2507 (0.32%)	6 / 2515 (0.24%)	
occurrences causally related to treatment / all	0 / 13	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical Device Site Infection			
subjects affected / exposed	1 / 2507 (0.04%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Myiasis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 2507 (0.16%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pancreas Infection			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Parotid Abscess			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	2 / 2507 (0.08%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	5 / 2507 (0.20%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	1 / 1	2 / 2	
Pharyngeal Abscess			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			

subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	68 / 2507 (2.71%)	72 / 2515 (2.86%)	
occurrences causally related to treatment / all	0 / 80	0 / 78	
deaths causally related to treatment / all	9 / 9	13 / 13	
Pneumonia Bacterial			
subjects affected / exposed	1 / 2507 (0.04%)	5 / 2515 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	2 / 2	
Pneumonia Klebsiella			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Staphylococcal			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Infection			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Postoperative Wound Infection			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			

subjects affected / exposed	2 / 2507 (0.08%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Acute			
subjects affected / exposed	0 / 2507 (0.00%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	2 / 2	
Pyuria			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection			
subjects affected / exposed	10 / 2507 (0.40%)	8 / 2515 (0.32%)	
occurrences causally related to treatment / all	0 / 10	0 / 9	
deaths causally related to treatment / all	1 / 1	0 / 0	
Sepsis			
subjects affected / exposed	16 / 2507 (0.64%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 16	0 / 7	
deaths causally related to treatment / all	7 / 7	2 / 2	
Septic Shock			
subjects affected / exposed	4 / 2507 (0.16%)	6 / 2515 (0.24%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	2 / 2	3 / 3	
Sinusitis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
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	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syphilis			

subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	5 / 2507 (0.20%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	14 / 2507 (0.56%)	9 / 2515 (0.36%)	
occurrences causally related to treatment / all	0 / 16	0 / 10	
deaths causally related to treatment / all	0 / 0	1 / 1	
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Myocarditis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	1 / 2507 (0.04%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	1 / 1	1 / 1	
Metabolism and nutrition disorders			
Acidosis			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Decreased Appetite			
subjects affected / exposed	0 / 2507 (0.00%)	2 / 2515 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 2507 (0.04%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus			
subjects affected / exposed	7 / 2507 (0.28%)	8 / 2515 (0.32%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	9 / 2507 (0.36%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Ketosis			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Metabolic Decompensation			
subjects affected / exposed	2 / 2507 (0.08%)	4 / 2515 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte Imbalance			

subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid Retention			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	3 / 2507 (0.12%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic Hyperosmolar Nonketotic Syndrome			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	4 / 2507 (0.16%)	7 / 2515 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hypervolaemia			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (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	5 / 2507 (0.20%)	5 / 2515 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			

subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 2507 (0.00%)	5 / 2515 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulin-Requiring Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 2507 (0.00%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic Acidosis			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic Disorder			
subjects affected / exposed	1 / 2507 (0.04%)	1 / 2515 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 Diabetes Mellitus			
subjects affected / exposed	1 / 2507 (0.04%)	0 / 2515 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 Diabetes Mellitus			
subjects affected / exposed	5 / 2507 (0.20%)	3 / 2515 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Rivaroxaban	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 2507 (2.11%)	60 / 2515 (2.39%)	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	53 / 2507 (2.11%)	60 / 2515 (2.39%)	
occurrences (all)	80	77	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported