



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. $\text{Event Rate} / (100 \text{ pt-yr}) = 100 * n / (\text{total risk exposure})$, 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) = $100 \cdot n / (\text{total risk exposure})$, 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) = $100 * n / (\text{total risk exposure})$, 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) = $100 * n / (\text{total risk exposure})$, 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) = $100 \cdot n / (\text{total risk exposure})$, 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) = $100 \cdot n / (\text{total risk exposure})$, 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) = $100 \cdot n / (\text{total risk exposure})$, 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) = $100 \cdot n / (\text{total risk exposure})$, 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
Gastroesophageal 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
Gastroesophageal 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
Gastroesophageal 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