Clinical trial results:
Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease (DD-CKD) (INNO2VATE – Conversion)

Summary

EudraCT number	2016-001360-11
Trial protocol	DE GB PT BG FR IT
Global end of trial date	16 January 2020

Results information

Result version number	v1 (current)
This version publication date	15 April 2021
First version publication date	15 April 2021

Trial information

Trial identification

Sponsor protocol code	AKB-6548-CI-0017

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02892149
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Akebia Therapeutics, Inc.
Sponsor organisation address	245 First Street, Suite 1400, Cambridge, Massachusetts, United States, 02142
Public contact	Clinical Trial Information Desk, Akebia Therapeutics, Inc., +1 617-844-6128, trials@akebia.com
Scientific contact	Steven Burke, Chief Medical Officer, Akebia Therapeutics, Inc., +1 617-844-6128, trials@akebia.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	16 January 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 January 2020
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 the efficacy and safety of vadadustat compared with darbepoetin alfa for the maintenance treatment of anemia in subjects with dialysis-dependent chronic kidney disease (DD-CKD).

Protection of trial subjects:

The study was conducted in full compliance with the principles of the "Declaration of Helsinki" (as amended in Tokyo, Venice, Hong Kong, and South Africa), International Council for Harmonisation (ICH) guidelines, and all of the applicable United States Code of Federal Regulations 21 (US CFR 21, CFR Part 50 and 312).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 August 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 88
Country: Number of subjects enrolled	Australia: 38
Country: Number of subjects enrolled	Brazil: 307
Country: Number of subjects enrolled	Bulgaria: 208
Country: Number of subjects enrolled	Canada: 48
Country: Number of subjects enrolled	France: 40
Country: Number of subjects enrolled	Germany: 17
Country: Number of subjects enrolled	Israel: 32
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 92
Country: Number of subjects enrolled	Mexico: 26
Country: Number of subjects enrolled	Poland: 76
Country: Number of subjects enrolled	Portugal: 30
Country: Number of subjects enrolled	Russian Federation: 92
Country: Number of subjects enrolled	Serbia: 131
Country: Number of subjects enrolled	Ukraine: 120
Country: Number of subjects enrolled	United Kingdom: 21

Country: Number of subjects enrolled	United States: 2176
Worldwide total number of subjects	3554
EEA total number of subjects	383

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)	2328
From 65 to 84 years	1174
85 years and over	52

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 4944 subjects were screened for entry into the study. Of these, 3554 subjects were enrolled and randomized in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Vadadustat

Arm description:

Subjects were randomized to receive vadadustat at an initial oral dose of 300 milligrams per day (mg/day). Thereafter, vadadustat was taken once daily on an outpatient basis. Up-and-down titration to 150, 300, 450, and 600 mg (available tablet strength was administered as the appropriate number of 150 mg tablets) was allowed during the study based on hemoglobin (Hb) level measurements every 4 weeks to maintain target Hb levels.

Arm type	Experimental
Investigational medicinal product name	Vadadustat
Investigational medicinal product code	AKB-6548
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150 mg white to off-white, round, bi-convex film-coated tablets for oral administration with a starting dose of 300 mg/day

Arm title	Darbepoetin Alfa

Arm description:

Subjects were randomized to darbepoetin alfa at an initial dose that was based on the current package insert for investigational sites in the United States (US), and the Summary of Product Characteristics (SmPC) for all other investigational sites (non-US) for adult subjects with chronic kidney disease on dialysis. For subjects already on darbepoetin alfa, the initial dosing regimen in the study was based on the prior dosing regimen.

Arm type	Active comparator
Investigational medicinal product name	Darbepoetin Alfa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intravenous bolus use

Dosage and administration details:

pre-filled syringes as an injectable solution for intravenous (IV) administration

Investigational medicinal product name	Darbepoetin Alfa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:
pre-filled syringes as an injectable solution for subcutaneous (SC) administration

Number of subjects in period 1	Vadadustat	Darbepoetin Alfa
Started	1777	1777
Completed	1425	1421
Not completed	352	356
Consent withdrawn by subject	53	47
Death	262	278
Lost to follow-up	37	31

Baseline characteristics

Reporting groups	
Reporting group title	Vadadustat

Reporting group description:

Subjects were randomized to receive vadadustat at an initial oral dose of 300 milligrams per day (mg/day). Thereafter, vadadustat was taken once daily on an outpatient basis. Up-and-down titration to 150, 300, 450, and 600 mg (available tablet strength was administered as the appropriate number of 150 mg tablets) was allowed during the study based on hemoglobin (Hb) level measurements every 4 weeks to maintain target Hb levels.

Reporting group title	Darbepoetin Alfa

Reporting group description:

Subjects were randomized to darbepoetin alfa at an initial dose that was based on the current package insert for investigational sites in the United States (US), and the Summary of Product Characteristics (SmPC) for all other investigational sites (non-US) for adult subjects with chronic kidney disease on dialysis. For subjects already on darbepoetin alfa, the initial dosing regimen in the study was based on the prior dosing regimen.

Reporting group values	Vadadustat	Darbepoetin Alfa	Total
Number of subjects	1777	1777	3554
Age categorical			
Units:			
Age continuous			
Units: years			
arithmetic mean	57.9	58.4	
standard deviation	± 13.86	± 13.84	-
Gender categorical			
Units: subjects			
Female	787	773	1560
Male	990	1004	1994
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	19	30	49
Asian	76	99	175
Black or African American	432	444	876
Native Hawaiian or Other Pacific Islander	13	6	19
White	1135	1096	2231
Not Reported	52	52	104
Reported as Other	42	45	87
Multiple	8	5	13
Average hemoglobin			
Units: milligrams per deciliter (mg/dL)			
arithmetic mean	10.249	10.229	
standard deviation	± 0.8502	± 0.8245	-

End points

End points reporting groups

Reporting group title	Vadadustat

Reporting group description:

Subjects were randomized to receive vadadustat at an initial oral dose of 300 milligrams per day (mg/day). Thereafter, vadadustat was taken once daily on an outpatient basis. Up-and-down titration to 150, 300, 450, and 600 mg (available tablet strength was administered as the appropriate number of 150 mg tablets) was allowed during the study based on hemoglobin (Hb) level measurements every 4 weeks to maintain target Hb levels.

Reporting group title	Darbepoetin Alfa

Reporting group description:

Subjects were randomized to darbepoetin alfa at an initial dose that was based on the current package insert for investigational sites in the United States (US), and the Summary of Product Characteristics (SmPC) for all other investigational sites (non-US) for adult subjects with chronic kidney disease on dialysis. For subjects already on darbepoetin alfa, the initial dosing regimen in the study was based on the prior dosing regimen.

Primary: Change in Average Hemoglobin (Hb) between Baseline and the Primary Efficacy Period (Weeks 24 to 36)

End point title	Change in Average Hemoglobin (Hb) between Baseline and the Primary Efficacy Period (Weeks 24 to 36)

End point description:

Change from Baseline was calculated as the Primary Efficacy Period value minus the Baseline value. The Primary Efficacy Period was comprised of Weeks 24 to 36. Analysis was conducted in members of the Randomized Population, comprised of all subjects randomized. Analyses of this population were based on the randomized treatment. Analysis was conducted using an analysis of covariance (ANCOVA) model with multiple imputation for missing data with Baseline hemoglobin concentration, region, and New York Heart Association congestive heart failure (NYHA CHF) class as covariates.

End point type	Primary

End point timeframe:

Baseline; Weeks 24 to 36

End point values	Vadadustat	Darbepoetin Alfa		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1777[1]	1777[2]		
Units: grams per deciliter (g/dL)				
least squares mean (standard error)	0.19 (± 0.032)	0.36 (± 0.032)		

Notes:

[1] - Randomized Population

[2] - Randomized Population

Statistical analyses

Statistical analysis title	ANCOVA with Multiple Imputation

Statistical analysis description:

Treatment Comparison: Vadadustat minus Darbepoetin Alfa

Comparison groups	Vadadustat v Darbepoetin Alfa

Number of subjects included in analysis	3554
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Least squares mean difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.03

Notes:

[3] - Establishment of non-inferiority was based on a margin of -0.75 g/dL applied to the difference in mean change: vadadustat minus darbepoetin alfa.

Secondary: Change in Average Hb Value between Baseline and the Secondary Efficacy Period (Weeks 40 to 52)

End point title	Change in Average Hb Value between Baseline and the Secondary Efficacy Period (Weeks 40 to 52)

End point description:

Change from Baseline was calculated as the Secondary Efficacy Period value minus the Baseline value. The Secondary Efficacy Period was comprised of Weeks 40 to 52. Analysis was conducted using an ANCOVA model with multiple imputation for missing data with Baseline hemoglobin concentration, region, and NYHA CHF class as covariates.

End point type	Secondary

End point timeframe:

Baseline; Weeks 40 to 52

End point values	Vadadustat	Darbepoetin Alfa		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1777[4]	1777[5]		
Units: g/dL				
least squares mean (standard error)	0.23 (± 0.035)	0.41 (± 0.033)		

Notes:

[4] - Randomized Population

[5] - Randomized Population

Statistical analyses

Statistical analysis title	ANCOVA with Multiple Imputation

Statistical analysis description:

Treatment Comparison: Vadadustat minus Darbepoetin Alfa

Comparison groups	Vadadustat v Darbepoetin Alfa

Number of subjects included in analysis	3554
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Least squares mean difference
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	-0.12
Variability estimate	Standard error of the mean
Dispersion value	0.04

Notes:

[6] - Establishment of non-inferiority was based on a margin of -0.75 g/dL applied to the difference in mean change: vadadustat minus darbepoetin alfa.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to approximately 168 weeks

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs), defined as adverse events (AEs) that began (or pre-existing AEs that worsened) on or after the first dose, are reported.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Vadadustat

Reporting group description:

Subjects were randomized to receive vadadustat at an initial oral dose of 300 milligrams per day (mg/day). Thereafter, vadadustat was taken once daily on an outpatient basis. Up-and-down titration to 150, 300, 450, and 600 mg (available tablet strength was administered as the appropriate number of 150 mg tablets) was allowed during the study based on hemoglobin (Hb) level measurements every 4 weeks to maintain target Hb levels.

Reporting group title	Darbepoetin Alfa

Reporting group description:

Subjects were randomized to darbepoetin alfa at an initial dose that was based on the current package insert for investigational sites in the United States (US), and the Summary of Product Characteristics (SmPC) for all other investigational sites (non-US) for adult subjects with chronic kidney disease on dialysis. For subjects already on darbepoetin alfa, the initial dosing regimen in the study was based on the prior dosing regimen.

Serious adverse events	Vadadustat	Darbepoetin Alfa	
Total subjects affected by serious adverse events			
subjects affected / exposed	973 / 1768 (55.03%)	1032 / 1769 (58.34%)	
number of deaths (all causes)	276	290	
number of deaths resulting from adverse events	266	276	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			

subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Adenocarcinoma of colon			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder cancer			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Papillary thyroid cancer			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borderline ovarian tumour			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carcinoid tumour			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular thyroid cancer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genitourinary tract neoplasm			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung squamous cell carcinoma metastatic			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed hepatocellular cholangiocarcinoma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma stage II			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neoplasm			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraneoplastic syndrome			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pelvic neoplasm			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mesothelioma malignant			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage II			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Refractory cytopenia with unilineage dysplasia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal adenoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma stage I			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma metastatic			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer metastatic			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	29 / 1768 (1.64%)	30 / 1769 (1.70%)	
occurrences causally related to treatment / all	0 / 32	0 / 33	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive urgency			
subjects affected / exposed	19 / 1768 (1.07%)	25 / 1769 (1.41%)	
occurrences causally related to treatment / all	0 / 20	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	20 / 1768 (1.13%)	22 / 1769 (1.24%)	
occurrences causally related to treatment / all	0 / 21	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	16 / 1768 (0.90%)	18 / 1769 (1.02%)	
occurrences causally related to treatment / all	0 / 21	1 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	12 / 1768 (0.68%)	13 / 1769 (0.73%)	
occurrences causally related to treatment / all	0 / 12	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	13 / 1768 (0.74%)	10 / 1769 (0.57%)	
occurrences causally related to treatment / all	1 / 13	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			

subjects affected / exposed	13 / 1768 (0.74%)	10 / 1769 (0.57%)	
occurrences causally related to treatment / all	0 / 16	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 1	
Peripheral arterial occlusive disease			
subjects affected / exposed	7 / 1768 (0.40%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Extremity necrosis			
subjects affected / exposed	8 / 1768 (0.45%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	7 / 1768 (0.40%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	9 / 1768 (0.51%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	8 / 1768 (0.45%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Aortic stenosis			
subjects affected / exposed	3 / 1768 (0.17%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	3 / 1768 (0.17%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 4	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			

subjects affected / exposed	5 / 1768 (0.28%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 2	
Dry gangrene			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	4 / 1768 (0.23%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 3	
Hypovolaemic shock			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Orthostatic hypotension			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steal syndrome			
subjects affected / exposed	4 / 1768 (0.23%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			

subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic vein occlusion			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous stenosis			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic vein thrombosis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein thrombosis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			

subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava occlusion			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accelerated hypertension			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial insufficiency			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Axillary vein thrombosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic vein stenosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Distributive shock			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery stenosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic limb pain			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrosis ischaemic			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic shock			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive shock			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral artery aneurysm			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post thrombotic syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein occlusion			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein stenosis			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subgaleal haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Superior vena cava stenosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stenosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis necrotising			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vein rupture			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Therapy cessation			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Arteriovenous fistula operation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodialysis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal polypectomy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procoagulant therapy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access placement			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breech presentation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cephalhaematoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature baby			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical incompetence			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	34 / 1768 (1.92%)	22 / 1769 (1.24%)	
occurrences causally related to treatment / all	0 / 35	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	24 / 1768 (1.36%)	14 / 1769 (0.79%)	
occurrences causally related to treatment / all	0 / 24	0 / 14	
deaths causally related to treatment / all	0 / 24	0 / 14	

Chest pain			
subjects affected / exposed	14 / 1768 (0.79%)	15 / 1769 (0.85%)	
occurrences causally related to treatment / all	0 / 18	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	6 / 1768 (0.34%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	3 / 1768 (0.17%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 3	0 / 9	
Pyrexia			
subjects affected / exposed	3 / 1768 (0.17%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 1768 (0.11%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 6	
Catheter site thrombosis			
subjects affected / exposed	5 / 1768 (0.28%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	1 / 5	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	6 / 1768 (0.34%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	4 / 1768 (0.23%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site haemorrhage			

subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Physical deconditioning			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Treatment noncompliance			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Catheter site pain			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			

subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical failure			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Catheter site inflammation			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site related reaction			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal syndrome			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia pain			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated hernia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue inflammation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media reaction			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant failure			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant rejection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Living in residential institution			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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			
Dysfunctional uterine bleeding			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Menorrhagia			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menometrorrhagia			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile vascular disorder			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst ruptured			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fluid collection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular oedema			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	44 / 1768 (2.49%)	50 / 1769 (2.83%)	
occurrences causally related to treatment / all	0 / 49	0 / 55	
deaths causally related to treatment / all	0 / 7	0 / 6	
Respiratory failure			

subjects affected / exposed	27 / 1768 (1.53%)	42 / 1769 (2.37%)	
occurrences causally related to treatment / all	0 / 32	0 / 42	
deaths causally related to treatment / all	0 / 2	0 / 9	
Pulmonary oedema			
subjects affected / exposed	26 / 1768 (1.47%)	33 / 1769 (1.87%)	
occurrences causally related to treatment / all	0 / 27	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	26 / 1768 (1.47%)	26 / 1769 (1.47%)	
occurrences causally related to treatment / all	0 / 30	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	19 / 1768 (1.07%)	13 / 1769 (0.73%)	
occurrences causally related to treatment / all	0 / 20	0 / 14	
deaths causally related to treatment / all	0 / 2	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	16 / 1768 (0.90%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 22	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	19 / 1768 (1.07%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 20	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	10 / 1768 (0.57%)	10 / 1769 (0.57%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	5 / 1768 (0.28%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	1 / 6	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			

subjects affected / exposed	5 / 1768 (0.28%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 1768 (0.11%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	4 / 1768 (0.23%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory arrest			
subjects affected / exposed	0 / 1768 (0.00%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
Respiratory distress			

subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory acidosis			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercapnia			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleurisy			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic disorder			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoventilation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal oedema			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung opacity			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal oedema			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Productive cough			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			

subjects affected / exposed	11 / 1768 (0.62%)	23 / 1769 (1.30%)	
occurrences causally related to treatment / all	0 / 11	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute psychosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute stress disorder			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Delirium tremens			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusion			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, visual			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuse			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	6 / 1768 (0.34%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device extrusion			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device leakage			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device physical property issue			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patient-device incompatibility			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	7 / 1768 (0.40%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	6 / 1768 (0.34%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cholecystitis			
subjects affected / exposed	7 / 1768 (0.40%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 1768 (0.06%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	4 / 1768 (0.23%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			

subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute hepatic failure			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis obstructive			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatic failure			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic haematoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic mass			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	7 / 1768 (0.40%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	7 / 1768 (0.40%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	1 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			

subjects affected / exposed	6 / 1768 (0.34%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	8 / 1768 (0.45%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
False positive investigation result			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ammonia increased			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza B virus test positive			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus test positive			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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			

Arteriovenous fistula thrombosis			
subjects affected / exposed	56 / 1768 (3.17%)	38 / 1769 (2.15%)	
occurrences causally related to treatment / all	2 / 66	7 / 46	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft thrombosis			
subjects affected / exposed	22 / 1768 (1.24%)	20 / 1769 (1.13%)	
occurrences causally related to treatment / all	1 / 28	1 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	17 / 1768 (0.96%)	18 / 1769 (1.02%)	
occurrences causally related to treatment / all	0 / 17	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site complication			
subjects affected / exposed	16 / 1768 (0.90%)	18 / 1769 (1.02%)	
occurrences causally related to treatment / all	0 / 17	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	11 / 1768 (0.62%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	15 / 1768 (0.85%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access malfunction			
subjects affected / exposed	10 / 1768 (0.57%)	10 / 1769 (0.57%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site thrombosis			
subjects affected / exposed	7 / 1768 (0.40%)	13 / 1769 (0.73%)	
occurrences causally related to treatment / all	0 / 8	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			

subjects affected / exposed	6 / 1768 (0.34%)	11 / 1769 (0.62%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	6 / 1768 (0.34%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Ankle fracture			
subjects affected / exposed	6 / 1768 (0.34%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	3 / 1768 (0.17%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft site haemorrhage			
subjects affected / exposed	4 / 1768 (0.23%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	6 / 1768 (0.34%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	2 / 1768 (0.11%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	4 / 1768 (0.23%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			

subjects affected / exposed	4 / 1768 (0.23%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	4 / 1768 (0.23%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 1768 (0.06%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm ruptured			
subjects affected / exposed	4 / 1768 (0.23%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula aneurysm			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft thrombosis			
subjects affected / exposed	5 / 1768 (0.28%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			

subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirenal haematoma			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pubis fracture			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula occlusion			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			

subjects affected / exposed	4 / 1768 (0.23%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft site stenosis			
subjects affected / exposed	0 / 1768 (0.00%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delayed graft function			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eschar			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 1768 (0.00%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			

subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal dialysis complication			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hypotension			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Procedural hypotension			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt thrombosis			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site pseudoaneurysm			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			

subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site haematoma			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Overdose			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative respiratory failure			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal lymphocele			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site complication			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft site haematoma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve replacement complication			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complications of transplanted kidney			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compression fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dialysis disequilibrium syndrome			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrostomy tube site complication			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site impaired healing			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site swelling			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation of wound			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation postoperative			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney rupture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal injury			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning deliberate			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post concussion syndrome			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural bile leak			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural diarrhoea			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discharge			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fever			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural swelling			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic pain			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative ileus			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural shock			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reactive gastropathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scapula fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin injury			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic fracture			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unintentional medical device removal			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access complication			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site rupture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Gastrointestinal arteriovenous malformation			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic arteriovenous malformation			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	81 / 1768 (4.58%)	78 / 1769 (4.41%)	
occurrences causally related to treatment / all	1 / 97	3 / 89	
deaths causally related to treatment / all	0 / 14	1 / 6	
Cardiac arrest			
subjects affected / exposed	49 / 1768 (2.77%)	60 / 1769 (3.39%)	
occurrences causally related to treatment / all	0 / 52	0 / 61	
deaths causally related to treatment / all	0 / 35	0 / 37	
Cardiac failure congestive			
subjects affected / exposed	45 / 1768 (2.55%)	50 / 1769 (2.83%)	
occurrences causally related to treatment / all	1 / 54	0 / 57	
deaths causally related to treatment / all	0 / 1	0 / 3	
Atrial fibrillation			
subjects affected / exposed	44 / 1768 (2.49%)	37 / 1769 (2.09%)	
occurrences causally related to treatment / all	0 / 49	0 / 43	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery disease			
subjects affected / exposed	28 / 1768 (1.58%)	32 / 1769 (1.81%)	
occurrences causally related to treatment / all	0 / 31	0 / 35	
deaths causally related to treatment / all	0 / 1	0 / 3	
Cardio-respiratory arrest			
subjects affected / exposed	28 / 1768 (1.58%)	26 / 1769 (1.47%)	
occurrences causally related to treatment / all	0 / 31	1 / 26	
deaths causally related to treatment / all	0 / 22	0 / 23	
Cardiac failure acute			

subjects affected / exposed	18 / 1768 (1.02%)	26 / 1769 (1.47%)	
occurrences causally related to treatment / all	0 / 22	0 / 29	
deaths causally related to treatment / all	0 / 3	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	13 / 1768 (0.74%)	23 / 1769 (1.30%)	
occurrences causally related to treatment / all	0 / 20	0 / 25	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiogenic shock			
subjects affected / exposed	10 / 1768 (0.57%)	14 / 1769 (0.79%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 4	0 / 9	
Myocardial infarction			
subjects affected / exposed	10 / 1768 (0.57%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 3	0 / 3	
Angina unstable			
subjects affected / exposed	8 / 1768 (0.45%)	13 / 1769 (0.73%)	
occurrences causally related to treatment / all	1 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	9 / 1768 (0.51%)	11 / 1769 (0.62%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Angina pectoris			
subjects affected / exposed	8 / 1768 (0.45%)	11 / 1769 (0.62%)	
occurrences causally related to treatment / all	0 / 8	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	9 / 1768 (0.51%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 2	
Atrial flutter			

subjects affected / exposed	6 / 1768 (0.34%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	4 / 1768 (0.23%)	11 / 1769 (0.62%)	
occurrences causally related to treatment / all	0 / 4	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	2 / 1768 (0.11%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 3	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	8 / 1768 (0.45%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 7	0 / 5	
Left ventricular failure			
subjects affected / exposed	4 / 1768 (0.23%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	2 / 1768 (0.11%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 2	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	2 / 1768 (0.11%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	4 / 1768 (0.23%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulseless electrical activity			

subjects affected / exposed	4 / 1768 (0.23%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 1768 (0.06%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Atrioventricular block complete			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic left ventricular failure			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 1768 (0.06%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	5 / 1768 (0.28%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery stenosis			

subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Sinus node dysfunction			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pericarditis			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			

subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial tachycardia			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery thrombosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic dysfunction			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal arrhythmia			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular arrhythmia			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Aortic valve disease			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorder			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiomegaly			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dressler's syndrome			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac mass			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular hypertrophy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve calcification			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis uraemic			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sinus bradycardia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular hypokinesia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Metabolic encephalopathy			
subjects affected / exposed	20 / 1768 (1.13%)	25 / 1769 (1.41%)	
occurrences causally related to treatment / all	0 / 22	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	22 / 1768 (1.24%)	18 / 1769 (1.02%)	
occurrences causally related to treatment / all	0 / 24	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			

subjects affected / exposed	14 / 1768 (0.79%)	16 / 1769 (0.90%)	
occurrences causally related to treatment / all	1 / 15	3 / 16	
deaths causally related to treatment / all	0 / 2	0 / 2	
Encephalopathy			
subjects affected / exposed	13 / 1768 (0.74%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 17	0 / 15	
deaths causally related to treatment / all	0 / 2	0 / 0	
Ischaemic stroke			
subjects affected / exposed	13 / 1768 (0.74%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 13	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 5	
Seizure			
subjects affected / exposed	6 / 1768 (0.34%)	14 / 1769 (0.79%)	
occurrences causally related to treatment / all	0 / 6	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	15 / 1768 (0.85%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	1 / 15	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	3 / 1768 (0.17%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 3	
Hepatic encephalopathy			
subjects affected / exposed	3 / 1768 (0.17%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	5 / 1768 (0.28%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Dizziness			

subjects affected / exposed	4 / 1768 (0.23%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cerebral infarction			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	2 / 1768 (0.11%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 1768 (0.06%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	5 / 1768 (0.28%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	4 / 1768 (0.23%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uraemic encephalopathy			

subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Altered state of consciousness			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain hypoxia			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Brain oedema			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Embolic stroke			

subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic encephalopathy			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lacunar infarction			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic cerebral infarction			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic seizure			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			

subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurotoxicity			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amputation stump pain			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia infarction			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system lupus			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery occlusion			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery thrombosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral microhaemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic hyperosmolar coma			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal dyscognitive seizures			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paralysis			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein occlusion			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microvascular cranial nerve palsy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post cardiac arrest syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postictal state			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	35 / 1768 (1.98%)	37 / 1769 (2.09%)	
occurrences causally related to treatment / all	2 / 38	0 / 40	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	16 / 1768 (0.90%)	24 / 1769 (1.36%)	
occurrences causally related to treatment / all	0 / 16	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	6 / 1768 (0.34%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	1 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicytopenia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow failure			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic uraemic syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic diathesis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic disorder			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macrocytosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic artery perforation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mydriasis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery thrombosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	34 / 1768 (1.92%)	29 / 1769 (1.64%)	
occurrences causally related to treatment / all	0 / 35	0 / 33	
deaths causally related to treatment / all	0 / 3	0 / 2	
Abdominal pain			
subjects affected / exposed	8 / 1768 (0.45%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatitis acute			
subjects affected / exposed	10 / 1768 (0.57%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	8 / 1768 (0.45%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			

subjects affected / exposed	9 / 1768 (0.51%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	2 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	5 / 1768 (0.28%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	1 / 5	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	7 / 1768 (0.40%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diarrhoea			
subjects affected / exposed	6 / 1768 (0.34%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	3 / 1768 (0.17%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	5 / 1768 (0.28%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	6 / 1768 (0.34%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 23	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	8 / 1768 (0.45%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 1	
Pancreatitis			

subjects affected / exposed	5 / 1768 (0.28%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	5 / 1768 (0.28%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Intestinal obstruction			
subjects affected / exposed	7 / 1768 (0.40%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Constipation			
subjects affected / exposed	6 / 1768 (0.34%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	6 / 1768 (0.34%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	2 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	2 / 1768 (0.11%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			

subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Melaena			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	1 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	4 / 1768 (0.23%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	1 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	5 / 1768 (0.28%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Faecaloma			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 1768 (0.00%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal haemorrhage			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal wall haematoma			

subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			

subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			

subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Gastric ulcer perforation				
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Gastrointestinal necrosis				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Haematemesis				
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Haemorrhagic erosive gastritis				
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Ileus paralytic				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Incarcerated umbilical hernia				
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Intra-abdominal haematoma				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Obstructive pancreatitis				

subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Umbilical hernia			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall oedema			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastropathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dieulafoy's vascular malformation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal polyp			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiectasia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal inflammation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal vascular malformation haemorrhagic			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal wall thickening			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia oral			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal perforation			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal ulcer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory bowel disease			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, obstructive			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal infarction			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal fluid collection			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal motility disorder			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis ulcerative			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic duct dilatation			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumoperitoneum			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal ulcer			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal ulcer haemorrhage			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uraemic gastropathy			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	7 / 1768 (0.40%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			

subjects affected / exposed	4 / 1768 (0.23%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	4 / 1768 (0.23%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Angioedema			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ulcer			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic skin ulcer			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous vasculitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hidradenitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urticaria			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
End stage renal disease			
subjects affected / exposed	15 / 1768 (0.85%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 15	0 / 9	
deaths causally related to treatment / all	0 / 11	0 / 6	
Azotaemia			
subjects affected / exposed	10 / 1768 (0.57%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 1	
Acute kidney injury			
subjects affected / exposed	4 / 1768 (0.23%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haematuria			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			

subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Nephrolithiasis			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic bladder			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst ruptured			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haemorrhage			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder rupture			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism secondary			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism tertiary			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal mass			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	5 / 1768 (0.28%)	9 / 1769 (0.51%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	5 / 1768 (0.28%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	7 / 1768 (0.40%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	5 / 1768 (0.28%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			

subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Arthralgia				
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Cervical spinal stenosis				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
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 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Neck pain				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Neuropathic arthropathy				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Osteitis				
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)		
occurrences causally related to treatment / all	0 / 1	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
Osteonecrosis				
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Spinal osteoarthritis				

subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone metabolism disorder			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease-mineral and bone disorder			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hungry bone syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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 / 1768 (0.06%)	0 / 1769 (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	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in jaw			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolysis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	140 / 1768 (7.92%)	119 / 1769 (6.73%)	
occurrences causally related to treatment / all	0 / 180	0 / 142	
deaths causally related to treatment / all	0 / 5	0 / 6	
Sepsis			
subjects affected / exposed	76 / 1768 (4.30%)	88 / 1769 (4.97%)	
occurrences causally related to treatment / all	0 / 83	0 / 96	
deaths causally related to treatment / all	0 / 13	0 / 13	
Septic shock			
subjects affected / exposed	44 / 1768 (2.49%)	45 / 1769 (2.54%)	
occurrences causally related to treatment / all	0 / 46	0 / 47	
deaths causally related to treatment / all	0 / 23	0 / 21	
Cellulitis			
subjects affected / exposed	43 / 1768 (2.43%)	38 / 1769 (2.15%)	
occurrences causally related to treatment / all	0 / 47	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	31 / 1768 (1.75%)	39 / 1769 (2.20%)	
occurrences causally related to treatment / all	0 / 35	0 / 47	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peritonitis			
subjects affected / exposed	21 / 1768 (1.19%)	32 / 1769 (1.81%)	
occurrences causally related to treatment / all	0 / 22	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 1	
Device related infection			
subjects affected / exposed	25 / 1768 (1.41%)	23 / 1769 (1.30%)	
occurrences causally related to treatment / all	0 / 25	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gangrene			
subjects affected / exposed	24 / 1768 (1.36%)	23 / 1769 (1.30%)	
occurrences causally related to treatment / all	0 / 31	0 / 26	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract infection			

subjects affected / exposed	15 / 1768 (0.85%)	32 / 1769 (1.81%)	
occurrences causally related to treatment / all	0 / 18	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	20 / 1768 (1.13%)	15 / 1769 (0.85%)	
occurrences causally related to treatment / all	0 / 21	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	16 / 1768 (0.90%)	18 / 1769 (1.02%)	
occurrences causally related to treatment / all	0 / 16	0 / 20	
deaths causally related to treatment / all	0 / 2	0 / 1	
Staphylococcal bacteraemia			
subjects affected / exposed	17 / 1768 (0.96%)	15 / 1769 (0.85%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	12 / 1768 (0.68%)	19 / 1769 (1.07%)	
occurrences causally related to treatment / all	0 / 12	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft site infection			
subjects affected / exposed	8 / 1768 (0.45%)	14 / 1769 (0.79%)	
occurrences causally related to treatment / all	0 / 9	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	8 / 1768 (0.45%)	14 / 1769 (0.79%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bacteraemia			
subjects affected / exposed	9 / 1768 (0.51%)	11 / 1769 (0.62%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			

subjects affected / exposed	5 / 1768 (0.28%)	15 / 1769 (0.85%)	
occurrences causally related to treatment / all	0 / 5	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 3	
Arteriovenous fistula site infection			
subjects affected / exposed	12 / 1768 (0.68%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 14	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	7 / 1768 (0.40%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	7 / 1768 (0.40%)	12 / 1769 (0.68%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	9 / 1768 (0.51%)	10 / 1769 (0.57%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	5 / 1768 (0.28%)	13 / 1769 (0.73%)	
occurrences causally related to treatment / all	0 / 5	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
Device related sepsis			
subjects affected / exposed	7 / 1768 (0.40%)	7 / 1769 (0.40%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	7 / 1768 (0.40%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			

subjects affected / exposed	3 / 1768 (0.17%)	8 / 1769 (0.45%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	4 / 1768 (0.23%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	5 / 1768 (0.28%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	5 / 1768 (0.28%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	4 / 1768 (0.23%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	4 / 1768 (0.23%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cytomegalovirus infection			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	1 / 1768 (0.06%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis bacterial			

subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 1768 (0.06%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arthritis bacterial			
subjects affected / exposed	2 / 1768 (0.11%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal peritonitis			
subjects affected / exposed	3 / 1768 (0.17%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	2 / 1768 (0.11%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			

subjects affected / exposed	3 / 1768 (0.17%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 1768 (0.06%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas gangrene			
subjects affected / exposed	0 / 1768 (0.00%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 1768 (0.06%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			

subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site infection			
subjects affected / exposed	0 / 1768 (0.00%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	3 / 1768 (0.17%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			

subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	0 / 1768 (0.00%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endocarditis staphylococcal			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			

subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	1 / 1768 (0.06%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal abscess			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	3 / 1768 (0.17%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenovirus infection			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast abscess			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site abscess			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatitis B			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal infection			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis bacterial			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft infection			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella infection			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Orchitis			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia serratia			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			

subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal graft infection			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Scrotal abscess			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal osteomyelitis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Streptococcal sepsis			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth infection			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			

subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval abscess			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Achromobacter infection			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical mycobacterial pneumonia			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial diarrhoea			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteriuria			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone abscess			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone tuberculosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis bacterial			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bullous impetigo			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida sepsis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis gangrenous			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral septic infarct			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corona virus infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis klebsiella			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous cholecystitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
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 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter sepsis			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fournier's gangrene			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital herpes			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giardiasis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site cellulitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site abscess			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected seroma			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium fortuitum infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis bacterial			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraspinal abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinephric abscess			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia moraxella			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas peritonitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyuria			

subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchitis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal abscess			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhodococcus infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic embolus			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic encephalopathy			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sialoadenitis			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infection			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic infection			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular abscess			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (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 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis viral			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant abscess			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel puncture site infection			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral diarrhoea			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral sepsis			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Fluid overload			
subjects affected / exposed	98 / 1768 (5.54%)	98 / 1769 (5.54%)	
occurrences causally related to treatment / all	0 / 138	0 / 132	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	55 / 1768 (3.11%)	76 / 1769 (4.30%)	
occurrences causally related to treatment / all	1 / 60	1 / 89	
deaths causally related to treatment / all	0 / 2	0 / 2	
Hypoglycaemia			
subjects affected / exposed	22 / 1768 (1.24%)	18 / 1769 (1.02%)	
occurrences causally related to treatment / all	0 / 23	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	6 / 1768 (0.34%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	6 / 1768 (0.34%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	5 / 1768 (0.28%)	6 / 1769 (0.34%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	5 / 1768 (0.28%)	5 / 1769 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypocalcaemia			
subjects affected / exposed	6 / 1768 (0.34%)	3 / 1769 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	3 / 1768 (0.17%)	4 / 1769 (0.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	2 / 1768 (0.11%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calciphylaxis			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	2 / 1768 (0.11%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dehydration			

subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 1768 (0.00%)	2 / 1769 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Failure to thrive			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolic acidosis			
subjects affected / exposed	1 / 1768 (0.06%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	2 / 1768 (0.11%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemosiderosis			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperphosphataemia			

subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic disorder			
subjects affected / exposed	0 / 1768 (0.00%)	1 / 1769 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 1768 (0.06%)	0 / 1769 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Vadadustat	Darbepoetin Alfa	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	964 / 1768 (54.52%)	993 / 1769 (56.13%)	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	136 / 1768 (7.69%)	144 / 1769 (8.14%)	
occurrences (all)	184	201	
Dialysis related complication			
subjects affected / exposed	99 / 1768 (5.60%)	122 / 1769 (6.90%)	
occurrences (all)	141	224	
Arteriovenous fistula site complication			

subjects affected / exposed	80 / 1768 (4.52%)	107 / 1769 (6.05%)	
occurrences (all)	134	144	
Vascular disorders			
Hypertension			
subjects affected / exposed	175 / 1768 (9.90%)	232 / 1769 (13.11%)	
occurrences (all)	219	300	
Hypotension			
subjects affected / exposed	124 / 1768 (7.01%)	119 / 1769 (6.73%)	
occurrences (all)	188	170	
Nervous system disorders			
Headache			
subjects affected / exposed	160 / 1768 (9.05%)	134 / 1769 (7.57%)	
occurrences (all)	331	207	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	226 / 1768 (12.78%)	173 / 1769 (9.78%)	
occurrences (all)	264	219	
Nausea			
subjects affected / exposed	148 / 1768 (8.37%)	131 / 1769 (7.41%)	
occurrences (all)	190	161	
Vomiting			
subjects affected / exposed	119 / 1768 (6.73%)	123 / 1769 (6.95%)	
occurrences (all)	142	150	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	99 / 1768 (5.60%)	120 / 1769 (6.78%)	
occurrences (all)	124	143	
Dyspnoea			
subjects affected / exposed	79 / 1768 (4.47%)	111 / 1769 (6.27%)	
occurrences (all)	94	133	
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	84 / 1768 (4.75%)	113 / 1769 (6.39%)	
occurrences (all)	110	132	
Back pain			

subjects affected / exposed	71 / 1768 (4.02%)	92 / 1769 (5.20%)	
occurrences (all)	89	110	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	98 / 1768 (5.54%)	108 / 1769 (6.11%)	
occurrences (all)	118	123	
Urinary tract infection			
subjects affected / exposed	100 / 1768 (5.66%)	93 / 1769 (5.26%)	
occurrences (all)	114	135	
Nasopharyngitis			
subjects affected / exposed	92 / 1768 (5.20%)	84 / 1769 (4.75%)	
occurrences (all)	131	108	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	123 / 1768 (6.96%)	137 / 1769 (7.74%)	
occurrences (all)	148	159	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 June 2017	• Updated the study design from the current screening period of up to 4 weeks to up to 8 weeks and allowed iron, vitamin B12, and folate supplementation as needed during the screening period. o Screening period changed from up to 4 weeks to up to 8 weeks. o One retest was allowed for each laboratory parameter, within the screening period. o Subjects who received iron replacement therapy may have had a retest screening hemoglobin (Hb) a minimum of 3 weeks after completion of iron replacement therapy. • Updated Exclusion Criteria • Vadadustat dosing and dose adjustment guidelines were updated to clarify that subjects who received 1 tablet of dosing prior to interruption resumed treatment with 1 tablet after interruption. • Updated to reflect information from recently completed studies. • Section 6.4.1 (Executive Steering Committee) details were added. • To clarify darbepoetin alfa administration and accountability, the following details were added: o Darbepoetin alfa was administered per the label; o Darbepoetin alfa doses may have been self-administered or administered by health care professional at the clinics, site facility, or at subject's home according to the investigator's determination and local practice; o Added additional information on return of darbepoetin alfa for drug accountability and compliance assessment. • Section 9.2.2 (Laboratory Evaluations) was revised to reflect the following: o Modification to the frequency of protocol-specified biomarker sample collection. o Additional exploratory sample collection. • Section 11.2 (Study Analysis Populations) clarified the study analysis populations.

18 January 2018	• Updated to reflect information from recently completed studies and for alignment with vadadustat Investigator's Brochure. • Updated to reflect addition of endpoints in alignment with the Statistical Analysis Plan. • Updated with an increase in enrollment number. • Section 7.4.1 Retesting was updated for simplification. • Updated to add Lack of Efficacy as a reason for permanent discontinuation of study drug or study participation. • Clarified that all enrolled subjects in this study will have completed (at least) the Week 36 visit. • Revised to guide investigators to follow printed dose adjustment algorithms. • Updated to align with published guidelines to prescribe iron supplementation and for initiation of ESA rescue. • Updated to specify a dosing compliance range of 80% to 120%. • Updated to clarify that if the screening period was less than 30 days, all medications taken within 30 days prior to first dose of study drug were to be recorded. • Updated to require monthly monitoring of Hb drawn as part of local standard of care or via an unscheduled visit. • Updated to require that all new and recurrent malignancies (with a few exceptions) be reported as serious adverse events (SAEs) to standardize reporting. • Updated to define overdose of study drugs. • Updated to reflect a change in the non inferiority margin from -0.5 to -1.0 g/dL. • Updated with enrollment projections and median study drug exposure times. • Updated definition of missing data updated to align with the SAP. • Updated to prespecify key subgroups for subsequent analysis. • Updated to provide AE summaries for specific subgroups.
13 September 2018	• Revised subject numbering. • Clarified that all enrolled subjects were to be allowed to complete the primary efficacy period prior to global study completion. • Clarified procedures at time of global study completion. • Emphasized subjects to be followed through global study completion. • Stated that if study drug was temporarily interrupted for more than 60 days, the Medical Monitor had to be contacted before resuming study drug. • End of Treatment/Follow-up visits to be performed at the time of permanent discontinuation of study drug. • Updated to reflect all options that had to be considered by the investigator before a subject withdrew consent and all options available to the investigator to follow subjects that permanently discontinued study drug. • Detailed steps to identify subjects lost to follow-up. • Updated with information for which the study teams will remain blinded. • Clarified restarting of study drug after ESA rescue/red blood cell transfusion. • Provided clarity on study drug dosing following ESA administration. • Provided guidance on how to manage the concomitant use of statins with vadadustat. • Included details for AE collection. • Included detail on managing subjects that permanently stop study medication during the study. • Defined the End of Study assessments that documented subject status at the global study completion or at the time of subject withdrawal, or when subject is deemed lost to follow-up or upon death. • Added guidance on managing subjects who developed malignancy while on study drug. • Updated to reflect how Baseline was calculated for Hb. • Updated to reflect a change in the non-inferiority margin from -1.0 to -0.75 grams per deciliter (g/dL). • Modified to include an updated definition for the primary safety endpoint and how non-inferiority was established between treatment groups. • Added a definition of Full Analysis Set population. • Updated with use of analysis of covariance with multiple imputation.

18 December 2018	• Included reference to the Pharmacy Manual which provided further details on storage and managing temperature excursions. • Provided further guidance regarding concomitant use of simvastatin drug interactions with vadadustat. • Provided guidance regarding concomitant use of breast cancer resistance protein (BCRP) substrates with vadadustat. • Updated to reflect recent results of investigative toxicology studies. • Liver function tests (LFTs) were increased in Year 2, 3, and 4 to include Weeks 64, 88, 116, 140, 168, and 192.
26 February 2019	• Updated to include a reference to Study Drug Stopping Rules for management of subjects with alanine aminotransferase (ALT) and aspartate aminotransferase (AST) abnormalities. • Include the table of LFT results that would require permanent discontinuation of vadadustat. • Updated to exclude subjects with elevations in ALT or AST >3 times upper limit of normal (ULN) with an elevation of total serum bilirubin >2 times ULN from conditions of temporary discontinuation, as this is now a condition for permanent discontinuation. • Updated to include information defining designated medical events.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

None reported

Notes: