

**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
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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
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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
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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
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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 standard deviation	57.9 ± 13.86	58.4 ± 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 standard deviation	10.249 ± 0.8502	10.229 ± 0.8245	-

End points

End points reporting groups

Reporting group title	Vadadustat
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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
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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)
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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
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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
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Statistical analysis description:

Treatment Comparison: Vadadustat minus Darbepoetin Alfa

Comparison groups	Vadadustat v Darbepoetin Alfa
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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)
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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
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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
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Statistical analysis description:

Treatment Comparison: Vadadustat minus Darbepoetin Alfa

Comparison groups	Vadadustat v Darbepoetin Alfa
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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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.1
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Reporting groups

Reporting group title	Vadadustat
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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
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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 occurrences (all)	80 / 1768 (4.52%) 134	107 / 1769 (6.05%) 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 occurrences (all)	71 / 1768 (4.02%) 89	92 / 1769 (5.20%) 110	
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	98 / 1768 (5.54%) 118	108 / 1769 (6.11%) 123	
Urinary tract infection subjects affected / exposed occurrences (all)	100 / 1768 (5.66%) 114	93 / 1769 (5.26%) 135	
Nasopharyngitis subjects affected / exposed occurrences (all)	92 / 1768 (5.20%) 131	84 / 1769 (4.75%) 108	
Metabolism and nutrition disorders			
Hyperkalaemia subjects affected / exposed occurrences (all)	123 / 1768 (6.96%) 148	137 / 1769 (7.74%) 159	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 June 2017	<ul style="list-style-type: none">• 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.<ul style="list-style-type: none">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:<ul style="list-style-type: none">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:<ul style="list-style-type: none">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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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: