

**Clinical trial results:****A Randomised, Controlled, Open-Label, Multicenter, Parallel-Group Study to Assess All-Cause Mortality and Cardiovascular Morbidity in Patients with Chronic Kidney Disease on Dialysis and Those Not on Renal Replacement Therapy under Treatment with MIRCERA® or Reference ESAs****Summary**

EudraCT number	2007-005129-31
Trial protocol	DE GB BE CZ IT SE LT GR FR
Global end of trial date	27 July 2017

Results information

Result version number	v1 (current)
This version publication date	03 August 2018
First version publication date	03 August 2018

Trial information**Trial identification**

Sponsor protocol code	BH21260
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00773513
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	F. Hoffmann-La Roche AG, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.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	20 June 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	27 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to demonstrate non-inferiority of methoxy polyethylene glycol-epoetin beta (MIRCERA) versus reference erythropoiesis-stimulating agents (ESAs) in terms of a composite endpoint of all cause mortality and non-fatal cardiovascular events (myocardial infarction [MI], stroke).

Protection of trial subjects:

All subjects signed an informed consent form before participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 December 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Malaysia: 17
Country: Number of subjects enrolled	Philippines: 15
Country: Number of subjects enrolled	Taiwan: 43
Country: Number of subjects enrolled	Korea, Republic of: 16
Country: Number of subjects enrolled	Singapore: 44
Country: Number of subjects enrolled	Thailand: 54
Country: Number of subjects enrolled	Turkey: 60
Country: Number of subjects enrolled	Israel: 64
Country: Number of subjects enrolled	Australia: 148
Country: Number of subjects enrolled	Belgium: 95
Country: Number of subjects enrolled	Croatia: 135
Country: Number of subjects enrolled	Czech Republic: 74
Country: Number of subjects enrolled	France: 269
Country: Number of subjects enrolled	Germany: 281
Country: Number of subjects enrolled	United Kingdom: 257
Country: Number of subjects enrolled	Greece: 85
Country: Number of subjects enrolled	Italy: 412
Country: Number of subjects enrolled	Lithuania: 34
Country: Number of subjects enrolled	Poland: 173
Country: Number of subjects enrolled	Russian Federation: 37

Country: Number of subjects enrolled	Serbia: 81
Country: Number of subjects enrolled	Spain: 130
Country: Number of subjects enrolled	Sweden: 18
Country: Number of subjects enrolled	Argentina: 84
Country: Number of subjects enrolled	Brazil: 155
Country: Number of subjects enrolled	Mexico: 32
Country: Number of subjects enrolled	Panama: 12
Worldwide total number of subjects	2825
EEA total number of subjects	1963

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)	1407
From 65 to 84 years	1334
85 years and over	84

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The subject population consisted of adults (≥ 18 years old) with symptomatic anemia associated with chronic kidney disease (renal anemia).

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	Erythropoiesis Stimulating Agents

Arm description:

Participants received reference ESA according to approved label. No biosimilar ESAs were accepted in the study. The approved reference ESA compounds in the study were darbepoetin alfa, epoetin alfa and epoetin beta.

Arm type	Active comparator
Investigational medicinal product name	Darbepoetin alfa
Investigational medicinal product code	
Other name	Aranesp®, Nespo®, Aranest®
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use, Intravenous use

Dosage and administration details:

Darbepoetin alfa was administered as per approved label.

Investigational medicinal product name	Epoetin beta
Investigational medicinal product code	
Other name	Neorecormon®, Recormon®
Pharmaceutical forms	Injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Epoetin beta was administered as per approved label.

Investigational medicinal product name	Epoetin alfa
Investigational medicinal product code	
Other name	Eporex®, Epogen®, Epopen®, Erypo®
Pharmaceutical forms	Injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Epoetin alfa was administered as per approved label.

Arm title	Methoxy Polyethylene Glycol-Epoetin Beta
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Arm description:

Subjects not currently being treated with an ESA received 0.6 micrograms per kilogram (mcg/kg) methoxy polyethylene glycol-epoetin beta intravenously (iv) or subcutaneously (sc) once every 2 weeks for correction of renal anemia (target hemoglobin [Hb] 10-12 grams per deciliter [g/dL]). Subjects currently treated with an ESA received a starting dose of 120, 200 or 360 mcg/kg methoxy polyethylene glycol-epoetin beta iv or sc once monthly based on the calculated weekly ESA dose prior to the switch for maintenance of anemia treatment. Once corrected and in subjects currently being treated with an ESA, methoxy polyethylene glycol-epoetin beta was administered once monthly.

Arm type	Experimental
Investigational medicinal product name	Darbepoetin alfa
Investigational medicinal product code	
Other name	Aranesp®, Nespo®, Aranest®
Pharmaceutical forms	Injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Darbepoetin alfa was administered as per approved label.

Investigational medicinal product name	Epoetin alfa
Investigational medicinal product code	
Other name	Eprex®, Epogen®, Epopen®, Erypo®
Pharmaceutical forms	Injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Epoetin alfa was administered as per approved label.

Investigational medicinal product name	Methoxy polyethylene glycol-epoetin beta
Investigational medicinal product code	
Other name	Mircera®
Pharmaceutical forms	Injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Subjects who were currently not being treated with an ESA received methoxy polyethylene glycol-epoetin beta administered at a starting dose of 0.6 mcg/kg body weight once every 2 weeks. Subjects who were currently being treated with an ESA received methoxy polyethylene glycol-epoetin beta at a dose of 120, 200 or 360 mcg once monthly (based on ESA dose administered in Week -1).

Number of subjects in period 1	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta
	Started	1413
Completed	312	303
Not completed	1101	1109
Withdrew Consent	68	69
Renal Transplant	254	263
Reason Not Specified	159	126
Death	531	545
Adverse Event / Intercurrent Illness	40	48
Failure to Return	22	8
Insufficient Therapeutic Response	1	18
Refused Treatment / Did Not Cooperate	26	32

Baseline characteristics

Reporting groups

Reporting group title	Erythropoiesis Stimulating Agents
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Reporting group description:

Participants received reference ESA according to approved label. No biosimilar ESAs were accepted in the study. The approved reference ESA compounds in the study were darbepoetin alfa, epoetin alfa and epoetin beta.

Reporting group title	Methoxy Polyethylene Glycol-Epoetin Beta
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Reporting group description:

Subjects not currently being treated with an ESA received 0.6 micrograms per kilogram (mcg/kg) methoxy polyethylene glycol-epoetin beta intravenously (iv) or subcutaneously (sc) once every 2 weeks for correction of renal anemia (target hemoglobin [Hb] 10-12 grams per deciliter [g/dL]). Subjects currently treated with an ESA received a starting dose of 120, 200 or 360 mcg/kg methoxy polyethylene glycol-epoetin beta iv or sc once monthly based on the calculated weekly ESA dose prior to the switch for maintenance of anemia treatment. Once corrected and in subjects currently being treated with an ESA, methoxy polyethylene glycol-epoetin beta was administered once monthly.

Reporting group values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta	Total
Number of subjects	1413	1412	2825
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	62.6 ± 14.8	62.2 ± 15.0	-
Gender categorical Units: Subjects			
Female	581	605	1186
Male	832	807	1639
Race/Ethnicity, Customized Units: Subjects			
White	1221	1218	2439
Asian	111	119	230
Black or African American	40	37	77
Other	41	38	79

End points

End points reporting groups

Reporting group title	Erythropoiesis Stimulating Agents
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Reporting group description:

Participants received reference ESA according to approved label. No biosimilar ESAs were accepted in the study. The approved reference ESA compounds in the study were darbepoetin alfa, epoetin alfa and epoetin beta.

Reporting group title	Methoxy Polyethylene Glycol-Epoetin Beta
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Reporting group description:

Subjects not currently being treated with an ESA received 0.6 micrograms per kilogram (mcg/kg) methoxy polyethylene glycol-epoetin beta intravenously (iv) or subcutaneously (sc) once every 2 weeks for correction of renal anemia (target hemoglobin [Hb] 10-12 grams per deciliter [g/dL]). Subjects currently treated with an ESA received a starting dose of 120, 200 or 360 mcg/kg methoxy polyethylene glycol-epoetin beta iv or sc once monthly based on the calculated weekly ESA dose prior to the switch for maintenance of anemia treatment. Once corrected and in subjects currently being treated with an ESA, methoxy polyethylene glycol-epoetin beta was administered once monthly.

Primary: Time to Composite of All-Cause Mortality and Non-Fatal Cardiovascular Events (Myocardial Infarction, Stroke) Defined as Time Between First Dose of Study Medication and Date of Death or Non-Fatal Cardiovascular Events, Whichever Occurred First

End point title	Time to Composite of All-Cause Mortality and Non-Fatal Cardiovascular Events (Myocardial Infarction, Stroke) Defined as Time Between First Dose of Study Medication and Date of Death or Non-Fatal Cardiovascular Events, Whichever Occurred First
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End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment. Data are reported for subjects with an event.

End point type	Primary
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End point timeframe:

Baseline up to approximately 8.5 years

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: years				
median (confidence interval 95%)	5.1 (4.8 to 5.6)	5.1 (4.7 to 5.4)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Erythropoiesis Stimulating Agents v Methoxy Polyethylene Glycol-Epoetin Beta

Number of subjects included in analysis	2818
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
P-value	= 0.0039
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.15

Notes:

[1] - The critical alpha level for the non-inferiority test was 0.025. The pre-specified upper non-inferiority limit was 95% CI <1.20.

Secondary: Time to All-Cause Mortality

End point title	Time to All-Cause Mortality
End point description:	
The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment. Data are reported for subjects with an event.	
End point type	Secondary
End point timeframe:	
Baseline up to approximately 8.5 years	

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: years				
median (confidence interval 95%)	6.1 (5.6 to 6.5)	5.9 (5.5 to 6.5)		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Erythropoiesis Stimulating Agents v Methoxy Polyethylene Glycol-Epoetin Beta
Number of subjects included in analysis	2818
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.0166
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.19

Secondary: Time to Non-Fatal and Fatal Myocardial Infarction

End point title	Time to Non-Fatal and Fatal Myocardial Infarction
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End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment. Analysis was performed on data for subjects with an event. 9999 = median time to event was not reached.

End point type	Secondary
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End point timeframe:

Baseline up to approximately 8.5 years

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: years				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	Statistical Analysis 3
Comparison groups	Erythropoiesis Stimulating Agents v Methoxy Polyethylene Glycol-Epoetin Beta
Number of subjects included in analysis	2818
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.0219
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.19

Secondary: Time to Non-Fatal and Fatal Stroke

End point title	Time to Non-Fatal and Fatal Stroke
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End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment. Analysis was performed on data for subjects with an event. 9999 = median time to event was not reached.

End point type	Secondary
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End point timeframe:

Baseline up to approximately 8.5 years

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: years				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	Statistical Analysis 4
Comparison groups	Erythropoiesis Stimulating Agents v Methoxy Polyethylene Glycol-Epoetin Beta
Number of subjects included in analysis	2818
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.0459
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.25

Secondary: Time to Non-Fatal Cardiovascular Events (Myocardial Infarction or Stroke, Whichever Occurred First)

End point title	Time to Non-Fatal Cardiovascular Events (Myocardial Infarction or Stroke, Whichever Occurred First)
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End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment. Analysis was performed on data for subjects with an event. 9999 = median time to event was not reached.

End point type Secondary

End point timeframe:

Baseline up to approximately 8.5 years

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: years				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	Statistical Analysis 5
Comparison groups	Erythropoiesis Stimulating Agents v Methoxy Polyethylene Glycol-Epoetin Beta
Number of subjects included in analysis	2818
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.0048
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.12

Secondary: Percentage of Subjects With Anti-Erythropoietin Antibody-Mediated Pure Red Cell Aplasia (PRCA)

End point title Percentage of Subjects With Anti-Erythropoietin Antibody-Mediated Pure Red Cell Aplasia (PRCA)

End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment.

End point type Secondary

End point timeframe:

Baseline up to approximately 8.5 years

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Gastrointestinal Bleeding

End point title | Percentage of Subjects With Gastrointestinal Bleeding

End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose safety assessment.

End point type | Secondary

End point timeframe:

Baseline up to approximately 8.5 years

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: percentage of subjects				
number (not applicable)	11.1	11.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Thromboembolic Events

End point title | Percentage of Subjects With Thromboembolic Events

End point description:

The safety population included all subjects randomised (with the appropriate signed consent documentation), who received at least one dose of the trial medication and had at least one post-dose

safety assessment.

End point type	Secondary
End point timeframe:	
Baseline up to approximately 8.5 years	

End point values	Erythropoiesis Stimulating Agents	Methoxy Polyethylene Glycol-Epoetin Beta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1409	1409		
Units: percentage of subjects				
number (not applicable)	34.5	32.8		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 8.5 years.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	Methoxy Polyethylene Glycol-Epoetin Beta
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Reporting group description:

Subjects not currently being treated with an ESA received 0.6 micrograms per kilogram (mcg/kg) methoxy polyethylene glycol-epoetin beta intravenously (iv) or subcutaneously (sc) once every 2 weeks for correction of renal anemia (target hemoglobin [Hb] 10-12 grams per deciliter [g/dL]). Subjects currently treated with an ESA received a starting dose of 120, 200 or 360 mcg/kg methoxy polyethylene glycol-epoetin beta iv or sc once monthly based on the calculated weekly ESA dose prior to the switch for maintenance of anemia treatment. Once corrected and in subjects currently being treated with an ESA, methoxy polyethylene glycol-epoetin beta was administered once monthly.

Reporting group title	Erythropoiesis Stimulating Agents
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Reporting group description:

Participants received reference ESA according to approved label. No biosimilar ESAs were accepted in the study. The approved reference ESA compounds in the study were darbepoetin alfa, epoetin alfa and epoetin beta.

Serious adverse events	Methoxy Polyethylene Glycol-Epoetin Beta	Erythropoiesis Stimulating Agents	
Total subjects affected by serious adverse events			
subjects affected / exposed	1097 / 1409 (77.86%)	1123 / 1409 (79.70%)	
number of deaths (all causes)	558	557	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	8 / 1409 (0.57%)	6 / 1409 (0.43%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	6 / 1409 (0.43%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			

subjects affected / exposed	4 / 1409 (0.28%)	5 / 1409 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Renal cell carcinoma			
subjects affected / exposed	6 / 1409 (0.43%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	1 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	5 / 1409 (0.35%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Myelodysplastic syndrome			
subjects affected / exposed	6 / 1409 (0.43%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	2 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of skin			

subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	0 / 1409 (0.00%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Rectal cancer		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 3
Intestinal adenocarcinoma		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cancer metastatic		

subjects affected / exposed	4 / 1409 (0.28%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Skin cancer		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Colon cancer		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm malignant		

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant melanoma		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant pleural effusion		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to central nervous system		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Metastases to lung		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic carcinoma		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Pituitary tumour benign		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Transitional cell carcinoma		

subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder papilloma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone neoplasm		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Colorectal cancer		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric cancer		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Lung adenocarcinoma		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to bone		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Neuroendocrine tumour		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Papillary thyroid cancer		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer recurrent		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid adenoma		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer metastatic		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myeloid leukaemia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Acute myelomonocytic leukaemia		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Adenoma benign		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of epididymis		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign urinary tract neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma metastatic		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Brain neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm malignant		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cancer pain		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour of the duodenum		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour of the stomach		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoma in situ of penis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system lymphoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system neoplasm		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral hygroma		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix cancer metastatic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Choroid melanoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Connective tissue neoplasm		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ear neoplasm malignant		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial neoplasm		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Extranodal marginal zone B-cell lymphoma (malt type)		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder adenocarcinoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic neoplasm			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoacanthoma			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal papilloma			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant fibrous histiocytoma			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to peritoneum			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to spine			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic carcinoid tumour			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic gastric cancer			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelofibrosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm skin		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal adenocarcinoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oligodendroglioma		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paget's disease of nipple		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Parathyroid tumour benign		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic neoplasm		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma recurrent		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Rectal cancer recurrent		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory cytopenia with unilineage dysplasia			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma recurrent			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haemangioma			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular neoplasm			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thymoma			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tonsil cancer			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transitional cell cancer of renal pelvis and ureter metastatic			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transitional cell carcinoma urethra			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tumour haemorrhage			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder adenoma			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Peripheral ischaemia			
subjects affected / exposed	31 / 1409 (2.20%)	31 / 1409 (2.20%)	
occurrences causally related to treatment / all	1 / 39	0 / 36	
deaths causally related to treatment / all	0 / 4	0 / 5	
Peripheral arterial occlusive disease			
subjects affected / exposed	24 / 1409 (1.70%)	24 / 1409 (1.70%)	
occurrences causally related to treatment / all	0 / 26	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertension			
subjects affected / exposed	23 / 1409 (1.63%)	24 / 1409 (1.70%)	
occurrences causally related to treatment / all	1 / 33	2 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	16 / 1409 (1.14%)	18 / 1409 (1.28%)	
occurrences causally related to treatment / all	1 / 16	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 1	
Extremity necrosis			
subjects affected / exposed	10 / 1409 (0.71%)	13 / 1409 (0.92%)	
occurrences causally related to treatment / all	0 / 12	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypertensive crisis			
subjects affected / exposed	13 / 1409 (0.92%)	8 / 1409 (0.57%)	
occurrences causally related to treatment / all	0 / 14	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	12 / 1409 (0.85%)	8 / 1409 (0.57%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	9 / 1409 (0.64%)	11 / 1409 (0.78%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			

subjects affected / exposed	5 / 1409 (0.35%)	11 / 1409 (0.78%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
Deep vein thrombosis		
subjects affected / exposed	7 / 1409 (0.50%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	1 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	8 / 1409 (0.57%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	9 / 1409 (0.64%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Shock haemorrhagic		
subjects affected / exposed	5 / 1409 (0.35%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 3
Aortic aneurysm		
subjects affected / exposed	5 / 1409 (0.35%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Steal syndrome		
subjects affected / exposed	8 / 1409 (0.57%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	5 / 1409 (0.35%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		

subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	3 / 1409 (0.21%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Venous stenosis		
subjects affected / exposed	4 / 1409 (0.28%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 3
Aortic aneurysm rupture		
subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 4	0 / 1
Brachiocephalic vein stenosis		
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Angiopathy		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial disorder		

subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Granulomatosis with polyangiitis			
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Shock			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			

subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angiodysplasia		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dissection		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial haemorrhage		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial rupture		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brachiocephalic vein thrombosis		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic macroangiopathy		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian vein stenosis		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular calcification		

subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aneurysm		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic arteriosclerosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic thrombosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stenosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery dissection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic infarction		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ischaemia		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic limb pain		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphatic fistula		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphostasis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microangiopathy		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microscopic polyangiitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic venous thrombosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis necrotising			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous aneurysm			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Oral surgery			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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			
Death			
subjects affected / exposed	39 / 1409 (2.77%)	33 / 1409 (2.34%)	
occurrences causally related to treatment / all	0 / 39	0 / 33	
deaths causally related to treatment / all	0 / 39	0 / 33	

Sudden death		
subjects affected / exposed	44 / 1409 (3.12%)	26 / 1409 (1.85%)
occurrences causally related to treatment / all	0 / 44	0 / 26
deaths causally related to treatment / all	0 / 44	0 / 26
Pyrexia		
subjects affected / exposed	26 / 1409 (1.85%)	30 / 1409 (2.13%)
occurrences causally related to treatment / all	0 / 31	0 / 39
deaths causally related to treatment / all	0 / 1	0 / 1
General physical health deterioration		
subjects affected / exposed	12 / 1409 (0.85%)	16 / 1409 (1.14%)
occurrences causally related to treatment / all	0 / 17	0 / 17
deaths causally related to treatment / all	0 / 6	0 / 11
Chest pain		
subjects affected / exposed	10 / 1409 (0.71%)	13 / 1409 (0.92%)
occurrences causally related to treatment / all	1 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site haemorrhage		
subjects affected / exposed	7 / 1409 (0.50%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	3 / 1409 (0.21%)	11 / 1409 (0.78%)
occurrences causally related to treatment / all	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Asthenia		
subjects affected / exposed	2 / 1409 (0.14%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Inflammation		
subjects affected / exposed	5 / 1409 (0.35%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		

subjects affected / exposed	3 / 1409 (0.21%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 6
Complication associated with device		
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 4
Hyperthermia		
subjects affected / exposed	1 / 1409 (0.07%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Adverse drug reaction		
subjects affected / exposed	4 / 1409 (0.28%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device related thrombosis		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperpyrexia		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema due to renal disease		

subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling			
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site inflammation			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Accidental death			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Discomfort			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug intolerance			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysplasia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heteroplasia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Impaired healing			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site extravasation		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated hernia		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site extravasation		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site scab		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device pain		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mucosal ulceration		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema due to cardiac disease		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudocyst		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Surgical failure		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Treatment failure		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent restenosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent stenosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent thrombosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Vessel puncture site haematoma		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney transplant rejection			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft versus host disease			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune reconstitution inflammatory syndrome			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas transplant rejection			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic ovarian cyst			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			

subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal haemorrhage		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast mass		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Female genital tract fistula		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hysterocele		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Menorrhagia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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			
Pleural effusion			
subjects affected / exposed	22 / 1409 (1.56%)	22 / 1409 (1.56%)	
occurrences causally related to treatment / all	0 / 23	0 / 23	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-cardiogenic pulmonary oedema			
subjects affected / exposed	15 / 1409 (1.06%)	23 / 1409 (1.63%)	
occurrences causally related to treatment / all	0 / 18	0 / 35	
deaths causally related to treatment / all	0 / 1	0 / 3	
Dyspnoea			
subjects affected / exposed	16 / 1409 (1.14%)	14 / 1409 (0.99%)	
occurrences causally related to treatment / all	0 / 17	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pulmonary oedema			
subjects affected / exposed	18 / 1409 (1.28%)	12 / 1409 (0.85%)	
occurrences causally related to treatment / all	1 / 19	0 / 13	
deaths causally related to treatment / all	0 / 4	0 / 2	
Acute pulmonary oedema			
subjects affected / exposed	11 / 1409 (0.78%)	14 / 1409 (0.99%)	
occurrences causally related to treatment / all	0 / 12	0 / 18	
deaths causally related to treatment / all	0 / 3	0 / 4	
Chronic obstructive pulmonary disease			
subjects affected / exposed	12 / 1409 (0.85%)	11 / 1409 (0.78%)	
occurrences causally related to treatment / all	0 / 16	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 2	
Respiratory failure			
subjects affected / exposed	13 / 1409 (0.92%)	7 / 1409 (0.50%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 9	0 / 3	
Pneumonia aspiration			

subjects affected / exposed	8 / 1409 (0.57%)	9 / 1409 (0.64%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 3	
Epistaxis			
subjects affected / exposed	4 / 1409 (0.28%)	8 / 1409 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	5 / 1409 (0.35%)	9 / 1409 (0.64%)	
occurrences causally related to treatment / all	1 / 5	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 3	
Acute respiratory failure			
subjects affected / exposed	6 / 1409 (0.43%)	5 / 1409 (0.35%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 3	
Pulmonary congestion			
subjects affected / exposed	5 / 1409 (0.35%)	6 / 1409 (0.43%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung disorder			
subjects affected / exposed	4 / 1409 (0.28%)	5 / 1409 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	7 / 1409 (0.50%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Haemothorax			
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			

subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Respiratory arrest		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Asthma		
subjects affected / exposed	0 / 1409 (0.00%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory distress		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial disorder		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polyps		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary mass			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lung injury			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atelectasis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumopathy			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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	1 / 1409 (0.07%)	0 / 1409 (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 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal effusion		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mendelson's syndrome		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Nasal septum perforation		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Painful respiration		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary thrombosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Reflux laryngitis		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory depression			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	10 / 1409 (0.71%)	14 / 1409 (0.99%)	
occurrences causally related to treatment / all	0 / 12	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Delirium			
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sopor			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adjustment disorder			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Organic brain syndrome		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Suicide attempt		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abnormal behaviour		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute psychosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety disorder		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug abuse			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance-induced psychotic disorder			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	8 / 1409 (0.57%)	7 / 1409 (0.50%)	
occurrences causally related to treatment / all	1 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			
subjects affected / exposed	9 / 1409 (0.64%)	6 / 1409 (0.43%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			

subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device breakage			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device damage			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device extrusion			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	12 / 1409 (0.85%)	10 / 1409 (0.71%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			

subjects affected / exposed	7 / 1409 (0.50%)	13 / 1409 (0.92%)
occurrences causally related to treatment / all	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	8 / 1409 (0.57%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Cholangitis		
subjects affected / exposed	5 / 1409 (0.35%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Bile duct stone		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Cholestasis		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatic failure			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bile duct obstruction			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cirrhosis alcoholic			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder enlargement			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemobilia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic artery stenosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatotoxicity		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocholecystis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic hepatitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver disorder		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Weight decreased			
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulation time prolonged			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation abnormal			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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	77 / 1409 (5.46%)	110 / 1409 (7.81%)	
occurrences causally related to treatment / all	2 / 106	4 / 141	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arteriovenous fistula site complication			
subjects affected / exposed	47 / 1409 (3.34%)	57 / 1409 (4.05%)	
occurrences causally related to treatment / all	0 / 65	0 / 69	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	26 / 1409 (1.85%)	23 / 1409 (1.63%)	
occurrences causally related to treatment / all	0 / 27	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	23 / 1409 (1.63%)	16 / 1409 (1.14%)	
occurrences causally related to treatment / all	0 / 26	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft thrombosis			
subjects affected / exposed	23 / 1409 (1.63%)	13 / 1409 (0.92%)	
occurrences causally related to treatment / all	1 / 44	1 / 39	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	14 / 1409 (0.99%)	19 / 1409 (1.35%)	
occurrences causally related to treatment / all	0 / 15	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	
Procedural hypotension			
subjects affected / exposed	16 / 1409 (1.14%)	13 / 1409 (0.92%)	
occurrences causally related to treatment / all	0 / 17	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula aneurysm			
subjects affected / exposed	6 / 1409 (0.43%)	15 / 1409 (1.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	12 / 1409 (0.85%)	8 / 1409 (0.57%)	
occurrences causally related to treatment / all	0 / 12	1 / 8	
deaths causally related to treatment / all	0 / 3	0 / 2	
Hip fracture			

subjects affected / exposed	11 / 1409 (0.78%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	7 / 1409 (0.50%)	11 / 1409 (0.78%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 2
Rib fracture		
subjects affected / exposed	9 / 1409 (0.64%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	5 / 1409 (0.35%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Humerus fracture		
subjects affected / exposed	7 / 1409 (0.50%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	5 / 1409 (0.35%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	8 / 1409 (0.57%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	5 / 1409 (0.35%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		

subjects affected / exposed	3 / 1409 (0.21%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	7 / 1409 (0.50%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	4 / 1409 (0.28%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	4 / 1409 (0.28%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	5 / 1409 (0.35%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	2 / 1409 (0.14%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft site stenosis		
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	4 / 1409 (0.28%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal compression fracture		

subjects affected / exposed	6 / 1409 (0.43%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site haematoma			
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	5 / 1409 (0.35%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	1 / 1409 (0.07%)	5 / 1409 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			

subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
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	2 / 1409 (0.14%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass thrombosis			
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft site haemorrhage			
subjects affected / exposed	4 / 1409 (0.28%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			

subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal dialysis complication		
subjects affected / exposed	4 / 1409 (0.28%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Acetabulum fracture		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Fibula fracture		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stoma complication		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Perirenal haematoma		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		

subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Thermal burn		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft aneurysm		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft site haematoma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		

subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural haematoma			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face injury			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft haemorrhage			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hernia			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural intestinal perforation		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt aneurysm		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt stenosis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin wound		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal injury			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass occlusion			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula occlusion			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Avulsion fracture			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone contusion			

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone fissure		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve replacement complication		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complications of transplant surgery		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Complications of transplanted kidney		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device deployment issue		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dislocation of vertebra			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eschar			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Extensive interdialytic weight gain			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal anastomotic leak			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodialysis complication			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyphaema			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated incisional hernia			

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal anastomosis complication			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney rupture			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip injury			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Muscle strain			

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital haematoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery restenosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative delirium		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postpericardiotomy syndrome		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural dizziness		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypertension		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation proctitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic injury		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site haemorrhage		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal hernia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic coma		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Traumatic haemorrhage		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular access complication			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular bypass dysfunction			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasoplegia syndrome			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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			
Congenital cystic kidney disease			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital bladder anomaly			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nonketotic hyperglycinaemia			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosi s			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	63 / 1409 (4.47%)	74 / 1409 (5.25%)	
occurrences causally related to treatment / all	3 / 82	3 / 94	
deaths causally related to treatment / all	0 / 10	0 / 17	
Atrial fibrillation			
subjects affected / exposed	49 / 1409 (3.48%)	57 / 1409 (4.05%)	
occurrences causally related to treatment / all	0 / 58	0 / 66	
deaths causally related to treatment / all	0 / 1	0 / 3	
Myocardial infarction			
subjects affected / exposed	54 / 1409 (3.83%)	50 / 1409 (3.55%)	
occurrences causally related to treatment / all	4 / 62	1 / 54	
deaths causally related to treatment / all	1 / 25	0 / 16	
Cardiac arrest			
subjects affected / exposed	55 / 1409 (3.90%)	44 / 1409 (3.12%)	
occurrences causally related to treatment / all	1 / 55	0 / 45	
deaths causally related to treatment / all	1 / 52	0 / 37	
Angina pectoris			
subjects affected / exposed	35 / 1409 (2.48%)	37 / 1409 (2.63%)	
occurrences causally related to treatment / all	0 / 37	1 / 46	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure			

subjects affected / exposed	25 / 1409 (1.77%)	34 / 1409 (2.41%)
occurrences causally related to treatment / all	0 / 31	0 / 37
deaths causally related to treatment / all	0 / 12	0 / 13
Acute coronary syndrome		
subjects affected / exposed	29 / 1409 (2.06%)	25 / 1409 (1.77%)
occurrences causally related to treatment / all	0 / 32	0 / 30
deaths causally related to treatment / all	0 / 7	0 / 2
Cardiac failure congestive		
subjects affected / exposed	20 / 1409 (1.42%)	24 / 1409 (1.70%)
occurrences causally related to treatment / all	0 / 24	0 / 26
deaths causally related to treatment / all	0 / 4	0 / 4
Coronary artery disease		
subjects affected / exposed	20 / 1409 (1.42%)	24 / 1409 (1.70%)
occurrences causally related to treatment / all	1 / 22	0 / 27
deaths causally related to treatment / all	0 / 1	0 / 1
Angina unstable		
subjects affected / exposed	24 / 1409 (1.70%)	16 / 1409 (1.14%)
occurrences causally related to treatment / all	1 / 26	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial ischaemia		
subjects affected / exposed	17 / 1409 (1.21%)	21 / 1409 (1.49%)
occurrences causally related to treatment / all	0 / 20	0 / 21
deaths causally related to treatment / all	0 / 3	0 / 6
Bradycardia		
subjects affected / exposed	8 / 1409 (0.57%)	20 / 1409 (1.42%)
occurrences causally related to treatment / all	0 / 8	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 3
Cardio-respiratory arrest		
subjects affected / exposed	10 / 1409 (0.71%)	12 / 1409 (0.85%)
occurrences causally related to treatment / all	1 / 12	0 / 12
deaths causally related to treatment / all	1 / 8	0 / 9
Aortic valve stenosis		

subjects affected / exposed	8 / 1409 (0.57%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Atrioventricular block complete		
subjects affected / exposed	9 / 1409 (0.64%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery stenosis		
subjects affected / exposed	9 / 1409 (0.64%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	5 / 1409 (0.35%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 7
Atrial flutter		
subjects affected / exposed	4 / 1409 (0.28%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	9 / 1409 (0.64%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1
Cardiopulmonary failure		
subjects affected / exposed	8 / 1409 (0.57%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 6	0 / 3
Ventricular fibrillation		
subjects affected / exposed	7 / 1409 (0.50%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 2
Arrhythmia		

subjects affected / exposed	2 / 1409 (0.14%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1
Left ventricular failure		
subjects affected / exposed	4 / 1409 (0.28%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure chronic		
subjects affected / exposed	2 / 1409 (0.14%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	1 / 1409 (0.07%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Sinus node dysfunction		
subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachycardia		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		

subjects affected / exposed	0 / 1409 (0.00%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial thrombosis			
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery thrombosis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
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	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis uraemic			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adams-Stokes syndrome			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac dysfunction		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Chordae tendinae rupture		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Conduction disorder		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery dissection		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic cardiomyopathy			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve incompetence			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve stenosis			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low cardiac output syndrome			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mitral valve stenosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paroxysmal atrioventricular block		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sinoatrial block		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Stress cardiomyopathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tachycardia		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular dyssynchrony			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	21 / 1409 (1.49%)	28 / 1409 (1.99%)	
occurrences causally related to treatment / all	1 / 23	1 / 29	
deaths causally related to treatment / all	1 / 5	0 / 3	
Transient ischaemic attack			
subjects affected / exposed	30 / 1409 (2.13%)	17 / 1409 (1.21%)	
occurrences causally related to treatment / all	2 / 31	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	24 / 1409 (1.70%)	23 / 1409 (1.63%)	
occurrences causally related to treatment / all	0 / 27	4 / 26	
deaths causally related to treatment / all	0 / 10	0 / 4	
Syncope			

subjects affected / exposed	15 / 1409 (1.06%)	22 / 1409 (1.56%)
occurrences causally related to treatment / all	0 / 15	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	8 / 1409 (0.57%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 5	0 / 5
Seizure		
subjects affected / exposed	5 / 1409 (0.35%)	10 / 1409 (0.71%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	9 / 1409 (0.64%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Dizziness		
subjects affected / exposed	9 / 1409 (0.64%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	3 / 1409 (0.21%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	6 / 1409 (0.43%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	3 / 1409 (0.21%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 3
Haemorrhage intracranial		

subjects affected / exposed	4 / 1409 (0.28%)	5 / 1409 (0.35%)	
occurrences causally related to treatment / all	0 / 4	1 / 5	
deaths causally related to treatment / all	0 / 4	0 / 2	
Dementia			
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	3 / 1409 (0.21%)	5 / 1409 (0.35%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Carotid artery stenosis			
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			

subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Presyncope			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic stroke			
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Altered state of consciousness			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Stupor			

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem infarction			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Generalised tonic-clonic seizure			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			

subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraventricular haemorrhage			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Lacunar infarction			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensorimotor neuropathy			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			

subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain hypoxia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Brain injury		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ataxia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebral small vessel ischaemic disease		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelination			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic mononeuropathy			

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Essential tremor		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia homonymous		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemic seizure		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic seizure		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic neuropathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
IVth nerve paresis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monoparesis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Movement disorder		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myoclonic epilepsy		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root compression		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nervous system disorder		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Noninfective encephalitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retrograde amnesia		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reversible ischaemic neurological deficit		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Somnolence		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal subarachnoid haemorrhage		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamus haemorrhage			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive to stimuli			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wallerian degeneration			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	25 / 1409 (1.77%)	22 / 1409 (1.56%)	
occurrences causally related to treatment / all	1 / 27	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemolysis			

subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bone marrow failure		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Anaemia of chronic disease		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia of malignant disease		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated intravascular coagulation		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lymphadenopathy		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spontaneous haematoma		

subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone marrow toxicity		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile bone marrow aplasia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolytic anaemia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Histiocytosis haematophagic		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic anaemia			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous haemorrhage			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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 / 1409 (0.14%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			

subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute vestibular syndrome			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo labyrinthine			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	10 / 1409 (0.71%)	9 / 1409 (0.64%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract diabetic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endocrine ophthalmopathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular vasculitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloedema		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal neovascularisation		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein thrombosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vision blurred		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haematoma			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	24 / 1409 (1.70%)	23 / 1409 (1.63%)	
occurrences causally related to treatment / all	0 / 26	1 / 27	
deaths causally related to treatment / all	0 / 2	0 / 3	
Abdominal pain			
subjects affected / exposed	13 / 1409 (0.92%)	16 / 1409 (1.14%)	
occurrences causally related to treatment / all	0 / 14	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diarrhoea			
subjects affected / exposed	18 / 1409 (1.28%)	9 / 1409 (0.64%)	
occurrences causally related to treatment / all	0 / 19	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	9 / 1409 (0.64%)	10 / 1409 (0.71%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	10 / 1409 (0.71%)	8 / 1409 (0.57%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			

subjects affected / exposed	5 / 1409 (0.35%)	11 / 1409 (0.78%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	7 / 1409 (0.50%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	10 / 1409 (0.71%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	8 / 1409 (0.57%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	7 / 1409 (0.50%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 3
Gastric ulcer haemorrhage		
subjects affected / exposed	6 / 1409 (0.43%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 2
Intestinal ischaemia		
subjects affected / exposed	5 / 1409 (0.35%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 5
Intestinal obstruction		
subjects affected / exposed	5 / 1409 (0.35%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 1
Melaena		

subjects affected / exposed	7 / 1409 (0.50%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Colitis		
subjects affected / exposed	5 / 1409 (0.35%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis acute		
subjects affected / exposed	3 / 1409 (0.21%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	6 / 1409 (0.43%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	4 / 1409 (0.28%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Abdominal pain upper		
subjects affected / exposed	3 / 1409 (0.21%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	6 / 1409 (0.43%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	3 / 1409 (0.21%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		

subjects affected / exposed	7 / 1409 (0.50%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	1 / 1409 (0.07%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulum		
subjects affected / exposed	2 / 1409 (0.14%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	5 / 1409 (0.35%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Enteritis		
subjects affected / exposed	2 / 1409 (0.14%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Vomiting		
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		

subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic		
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	1 / 1409 (0.07%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhoids		
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal infarction		
subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 4
Gastrointestinal disorder		
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		

subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroesophageal reflux disease		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	4 / 1409 (0.28%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		

subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Abdominal discomfort		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Anal fistula		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Encapsulating peritoneal sclerosis		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric antral vascular ectasia		

subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiectasia		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Large intestinal ulcer haemorrhage		
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising colitis		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis erosive			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous fistula			
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive duodenitis			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
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	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal perforation		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haemorrhage			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal stenosis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal ulcer			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal varices			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal mucocoele			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Defaecation urgency			

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastropathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum oesophageal		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis haemorrhagic		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Flatulence		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallstone ileus		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal hypomotility		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Inguinal hernia strangulated		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal angina		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal mass		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal pseudo-obstruction		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal varices		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal fluid collection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic enteritis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Large intestinal stenosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar hernia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric arterial occlusion		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Nausea		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal spasm		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis haemorrhagic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral disorder		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer perforation		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland enlargement			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue oedema			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, obstructive			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Strangulated umbilical hernia			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin ulcer			

subjects affected / exposed	17 / 1409 (1.21%)	17 / 1409 (1.21%)
occurrences causally related to treatment / all	0 / 20	0 / 18
deaths causally related to treatment / all	0 / 1	0 / 0
Diabetic foot		
subjects affected / exposed	11 / 1409 (0.78%)	13 / 1409 (0.92%)
occurrences causally related to treatment / all	0 / 13	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Skin necrosis		
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic skin ulcer		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Drug eruption		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Decubitus ulcer		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Panniculitis		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyoderma gangrenosum		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stasis dermatitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute generalised exanthematous pustulosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestatic pruritus		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermal cyst		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis exfoliative		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ulcer		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug reaction with eosinophilia and systemic symptoms		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Erythema multiforme			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin erosion			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitic rash			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	26 / 1409 (1.85%)	31 / 1409 (2.20%)	
occurrences causally related to treatment / all	0 / 26	0 / 31	
deaths causally related to treatment / all	0 / 26	0 / 29	
Renal impairment			
subjects affected / exposed	18 / 1409 (1.28%)	20 / 1409 (1.42%)	
occurrences causally related to treatment / all	2 / 18	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haematuria			
subjects affected / exposed	8 / 1409 (0.57%)	7 / 1409 (0.50%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	4 / 1409 (0.28%)	7 / 1409 (0.50%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 3	0 / 1	
Azotaemia			
subjects affected / exposed	6 / 1409 (0.43%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			

subjects affected / exposed	3 / 1409 (0.21%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Nephrolithiasis		
subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst haemorrhage		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Renal colic		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		

subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder polyp		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder tamponade		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis interstitial		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage urinary tract		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney enlargement		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lupus nephritis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition-inflammation-atherosclerosis syndrome		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Nephritis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst ruptured		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haematoma		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal ischaemia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urethral stenosis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperparathyroidism secondary			
subjects affected / exposed	23 / 1409 (1.63%)	19 / 1409 (1.35%)	
occurrences causally related to treatment / all	0 / 24	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism tertiary			
subjects affected / exposed	4 / 1409 (0.28%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal insufficiency			

subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	3 / 1409 (0.21%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basedow's disease			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid hyperplasia			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	16 / 1409 (1.14%)	19 / 1409 (1.35%)	
occurrences causally related to treatment / all	0 / 17	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	8 / 1409 (0.57%)	4 / 1409 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	2 / 1409 (0.14%)	9 / 1409 (0.64%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			

subjects affected / exposed	2 / 1409 (0.14%)	6 / 1409 (0.43%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	3 / 1409 (0.21%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	0 / 1409 (0.00%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic lupus erythematosus		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			

subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteolysis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic fracture		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arthrofibrosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondropathy		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease-mineral and bone disorder		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Collagen disorder		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Compartment syndrome		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibromyalgia		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
High turnover osteopathy		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle necrosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plantar fasciitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthrititis		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcopenia			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sympathetic posterior cervical syndrome			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torticollis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	180 / 1409 (12.78%)	163 / 1409 (11.57%)
occurrences causally related to treatment / all	1 / 228	0 / 205
deaths causally related to treatment / all	0 / 27	0 / 19
Sepsis		
subjects affected / exposed	69 / 1409 (4.90%)	85 / 1409 (6.03%)
occurrences causally related to treatment / all	0 / 79	1 / 96
deaths causally related to treatment / all	0 / 26	1 / 39
Peritonitis		
subjects affected / exposed	47 / 1409 (3.34%)	46 / 1409 (3.26%)
occurrences causally related to treatment / all	0 / 62	0 / 70
deaths causally related to treatment / all	0 / 2	0 / 2
Septic shock		
subjects affected / exposed	36 / 1409 (2.56%)	49 / 1409 (3.48%)
occurrences causally related to treatment / all	0 / 36	0 / 50
deaths causally related to treatment / all	0 / 27	0 / 34
Gastroenteritis		
subjects affected / exposed	39 / 1409 (2.77%)	27 / 1409 (1.92%)
occurrences causally related to treatment / all	0 / 49	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	31 / 1409 (2.20%)	33 / 1409 (2.34%)
occurrences causally related to treatment / all	0 / 35	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	21 / 1409 (1.49%)	30 / 1409 (2.13%)
occurrences causally related to treatment / all	0 / 29	0 / 36
deaths causally related to treatment / all	0 / 2	0 / 3
Lower respiratory tract infection		
subjects affected / exposed	21 / 1409 (1.49%)	28 / 1409 (1.99%)
occurrences causally related to treatment / all	0 / 26	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 2
Cellulitis		

subjects affected / exposed	22 / 1409 (1.56%)	25 / 1409 (1.77%)
occurrences causally related to treatment / all	0 / 25	0 / 28
deaths causally related to treatment / all	0 / 1	0 / 0
Device related infection		
subjects affected / exposed	19 / 1409 (1.35%)	28 / 1409 (1.99%)
occurrences causally related to treatment / all	0 / 22	0 / 38
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	20 / 1409 (1.42%)	24 / 1409 (1.70%)
occurrences causally related to treatment / all	0 / 22	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	22 / 1409 (1.56%)	20 / 1409 (1.42%)
occurrences causally related to treatment / all	0 / 24	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory tract infection		
subjects affected / exposed	16 / 1409 (1.14%)	23 / 1409 (1.63%)
occurrences causally related to treatment / all	0 / 19	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 1
Staphylococcal sepsis		
subjects affected / exposed	14 / 1409 (0.99%)	18 / 1409 (1.28%)
occurrences causally related to treatment / all	0 / 16	0 / 20
deaths causally related to treatment / all	0 / 3	0 / 1
Urosepsis		
subjects affected / exposed	19 / 1409 (1.35%)	11 / 1409 (0.78%)
occurrences causally related to treatment / all	0 / 20	0 / 12
deaths causally related to treatment / all	0 / 5	0 / 1
Bacteraemia		
subjects affected / exposed	10 / 1409 (0.71%)	14 / 1409 (0.99%)
occurrences causally related to treatment / all	0 / 11	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriovenous fistula site infection		

subjects affected / exposed	9 / 1409 (0.64%)	14 / 1409 (0.99%)
occurrences causally related to treatment / all	0 / 10	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	15 / 1409 (1.06%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	10 / 1409 (0.71%)	10 / 1409 (0.71%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	10 / 1409 (0.71%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	5 / 1409 (0.35%)	13 / 1409 (0.92%)
occurrences causally related to treatment / all	0 / 6	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	10 / 1409 (0.71%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	1 / 12	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Endocarditis		
subjects affected / exposed	7 / 1409 (0.50%)	10 / 1409 (0.71%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 2
Catheter site infection		
subjects affected / exposed	4 / 1409 (0.28%)	10 / 1409 (0.71%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		

subjects affected / exposed	4 / 1409 (0.28%)	10 / 1409 (0.71%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	5 / 1409 (0.35%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	3 / 1409 (0.21%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft site infection		
subjects affected / exposed	4 / 1409 (0.28%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	3 / 1409 (0.21%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	3 / 1409 (0.21%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	3 / 1409 (0.21%)	8 / 1409 (0.57%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 1
Viral infection		
subjects affected / exposed	8 / 1409 (0.57%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	1 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		

subjects affected / exposed	5 / 1409 (0.35%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	6 / 1409 (0.43%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	5 / 1409 (0.35%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Localised infection		
subjects affected / exposed	5 / 1409 (0.35%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia bacterial		
subjects affected / exposed	5 / 1409 (0.35%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary sepsis		
subjects affected / exposed	2 / 1409 (0.14%)	7 / 1409 (0.50%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 4
Staphylococcal infection		
subjects affected / exposed	8 / 1409 (0.57%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	3 / 1409 (0.21%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		

subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	3 / 1409 (0.21%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Renal cyst infection		
subjects affected / exposed	4 / 1409 (0.28%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	1 / 1409 (0.07%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	1 / 1409 (0.07%)	5 / 1409 (0.35%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Cystitis		

subjects affected / exposed	2 / 1409 (0.14%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	5 / 1409 (0.35%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 1409 (0.21%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Abdominal abscess		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Abscess limb		
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 1409 (0.07%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		

subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal sepsis		
subjects affected / exposed	4 / 1409 (0.28%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Soft tissue infection		
subjects affected / exposed	2 / 1409 (0.14%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary sepsis		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal peritonitis		
subjects affected / exposed	4 / 1409 (0.28%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		

subjects affected / exposed	4 / 1409 (0.28%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
H1N1 influenza		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	1 / 1409 (0.07%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pyelonephritis chronic		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Acute sinusitis		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis infective		

subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
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	3 / 1409 (0.21%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 1409 (0.00%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pyonephrosis		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Septic necrosis		

subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Sialoadenitis			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal sepsis			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Appendicitis perforated			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arteriosclerotic gangrene			

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
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	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial infection		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Encephalitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis staphylococcal		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter sepsis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Fungal oesophagitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemophilus infection		

subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Joint tuberculosis		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Listeriosis		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymph node tuberculosis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Pneumonia klebsiella		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Proteus infection		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal graft infection		
subjects affected / exposed	2 / 1409 (0.14%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal abscess		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Septic arthritis staphylococcal		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Sinusitis		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Skin bacterial infection		

subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic candida			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall infection			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical mycobacterial infection		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial colitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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 / 1409 (0.07%)	0 / 1409 (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	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone tuberculosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopulmonary aspergillosis		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cat scratch disease			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site abscess			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic tonsillitis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Citrobacter sepsis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon gangrene			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
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	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal abscess		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Corynebacterium sepsis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis bacterial		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dacryocystitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia pyelonephritis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile infection		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Genitourinary tract infection		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst infection		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes sepsis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Herpes zoster meningoencephalitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bunion		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected dermal cyst		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected fistula		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective gastroduodenitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site infection		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fistula infection			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint abscess			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella infection			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Listeria encephalitis			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung abscess			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mesenteric abscess			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess			

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mycetoma mycotic		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nail infection		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nosocomial infection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal candidiasis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media acute		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic inflammatory disease		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perihepatic abscess		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontal destruction		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
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 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia necrotising		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (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 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia respiratory syncytial viral		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyomyositis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rotavirus infection		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salpingitis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seminal vesicle abscess		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subacute endocarditis		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubo-ovarian abscess			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral abscess			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection staphylococcal			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal infection			
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Fluid overload			
subjects affected / exposed	43 / 1409 (3.05%)	44 / 1409 (3.12%)	
occurrences causally related to treatment / all	1 / 52	0 / 50	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperkalaemia			

subjects affected / exposed	32 / 1409 (2.27%)	18 / 1409 (1.28%)
occurrences causally related to treatment / all	0 / 42	0 / 25
deaths causally related to treatment / all	0 / 1	0 / 1
Hypoglycaemia		
subjects affected / exposed	17 / 1409 (1.21%)	12 / 1409 (0.85%)
occurrences causally related to treatment / all	0 / 19	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 1
Cachexia		
subjects affected / exposed	10 / 1409 (0.71%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 10	0 / 7
Hyperglycaemia		
subjects affected / exposed	3 / 1409 (0.21%)	9 / 1409 (0.64%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Dehydration		
subjects affected / exposed	7 / 1409 (0.50%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	5 / 1409 (0.35%)	3 / 1409 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	6 / 1409 (0.43%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	4 / 1409 (0.28%)	4 / 1409 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0
Hypervolaemia		

subjects affected / exposed	4 / 1409 (0.28%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Calciphylaxis		
subjects affected / exposed	4 / 1409 (0.28%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic complication		
subjects affected / exposed	4 / 1409 (0.28%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	3 / 1409 (0.21%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	2 / 1409 (0.14%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	3 / 1409 (0.21%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 1409 (0.07%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		

subjects affected / exposed	2 / 1409 (0.14%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperinsulinaemic hypoglycaemia		
subjects affected / exposed	0 / 1409 (0.00%)	2 / 1409 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	1 / 1409 (0.07%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Decreased appetite		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemochromatosis		

subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoalbuminaemia		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophosphataemia		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic disorder		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitochondrial cytopathy		
subjects affected / exposed	0 / 1409 (0.00%)	1 / 1409 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Type 1 diabetes mellitus		

subjects affected / exposed	1 / 1409 (0.07%)	0 / 1409 (0.00%)
occurrences causally related to treatment / all	0 / 2	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	Methoxy Polyethylene Glycol-Epoetin Beta	Erythropoiesis Stimulating Agents
Total subjects affected by non-serious adverse events		
subjects affected / exposed	1177 / 1409 (83.53%)	1171 / 1409 (83.11%)
Vascular disorders		
Hypertension		
subjects affected / exposed	455 / 1409 (32.29%)	432 / 1409 (30.66%)
occurrences (all)	663	584
Hypotension		
subjects affected / exposed	124 / 1409 (8.80%)	143 / 1409 (10.15%)
occurrences (all)	158	175
General disorders and administration site conditions		
Pyrexia		
subjects affected / exposed	92 / 1409 (6.53%)	96 / 1409 (6.81%)
occurrences (all)	107	115
Oedema due to renal disease		
subjects affected / exposed	78 / 1409 (5.54%)	79 / 1409 (5.61%)
occurrences (all)	113	97
Asthenia		
subjects affected / exposed	85 / 1409 (6.03%)	59 / 1409 (4.19%)
occurrences (all)	100	67
Oedema peripheral		
subjects affected / exposed	61 / 1409 (4.33%)	73 / 1409 (5.18%)
occurrences (all)	67	79
Respiratory, thoracic and mediastinal disorders		
Cough		
subjects affected / exposed	162 / 1409 (11.50%)	194 / 1409 (13.77%)
occurrences (all)	242	274

Dyspnoea subjects affected / exposed occurrences (all)	109 / 1409 (7.74%) 129	109 / 1409 (7.74%) 132	
Epistaxis subjects affected / exposed occurrences (all)	50 / 1409 (3.55%) 62	72 / 1409 (5.11%) 99	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	104 / 1409 (7.38%) 109	116 / 1409 (8.23%) 124	
Depression subjects affected / exposed occurrences (all)	75 / 1409 (5.32%) 78	65 / 1409 (4.61%) 70	
Injury, poisoning and procedural complications Procedural hypotension subjects affected / exposed occurrences (all)	223 / 1409 (15.83%) 366	225 / 1409 (15.97%) 368	
Arteriovenous fistula site complication subjects affected / exposed occurrences (all)	158 / 1409 (11.21%) 231	171 / 1409 (12.14%) 262	
Arteriovenous fistula thrombosis subjects affected / exposed occurrences (all)	86 / 1409 (6.10%) 109	87 / 1409 (6.17%) 110	
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	111 / 1409 (7.88%) 125	123 / 1409 (8.73%) 154	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	141 / 1409 (10.01%) 199	127 / 1409 (9.01%) 187	
Dizziness subjects affected / exposed occurrences (all)	81 / 1409 (5.75%) 100	78 / 1409 (5.54%) 86	
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	174 / 1409 (12.35%) 205	143 / 1409 (10.15%) 176	
Eye disorders Cataract subjects affected / exposed occurrences (all)	76 / 1409 (5.39%) 87	72 / 1409 (5.11%) 82	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	273 / 1409 (19.38%) 434	269 / 1409 (19.09%) 387	
Constipation subjects affected / exposed occurrences (all)	142 / 1409 (10.08%) 162	173 / 1409 (12.28%) 205	
Vomiting subjects affected / exposed occurrences (all)	121 / 1409 (8.59%) 162	146 / 1409 (10.36%) 197	
Nausea subjects affected / exposed occurrences (all)	104 / 1409 (7.38%) 137	99 / 1409 (7.03%) 121	
Abdominal pain subjects affected / exposed occurrences (all)	102 / 1409 (7.24%) 134	88 / 1409 (6.25%) 99	
Abdominal pain upper subjects affected / exposed occurrences (all)	82 / 1409 (5.82%) 93	70 / 1409 (4.97%) 87	
Dyspepsia subjects affected / exposed occurrences (all)	59 / 1409 (4.19%) 71	78 / 1409 (5.54%) 88	
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	114 / 1409 (8.09%) 128	118 / 1409 (8.37%) 136	
Endocrine disorders Hyperparathyroidism secondary			

subjects affected / exposed	148 / 1409 (10.50%)	149 / 1409 (10.57%)	
occurrences (all)	165	157	
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	199 / 1409 (14.12%)	211 / 1409 (14.98%)	
occurrences (all)	298	311	
Back pain			
subjects affected / exposed	119 / 1409 (8.45%)	158 / 1409 (11.21%)	
occurrences (all)	140	186	
Pain in extremity			
subjects affected / exposed	124 / 1409 (8.80%)	133 / 1409 (9.44%)	
occurrences (all)	170	162	
Arthralgia			
subjects affected / exposed	125 / 1409 (8.87%)	110 / 1409 (7.81%)	
occurrences (all)	150	126	
Osteoarthritis			
subjects affected / exposed	86 / 1409 (6.10%)	105 / 1409 (7.45%)	
occurrences (all)	93	115	
Musculoskeletal pain			
subjects affected / exposed	72 / 1409 (5.11%)	79 / 1409 (5.61%)	
occurrences (all)	83	99	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	187 / 1409 (13.27%)	171 / 1409 (12.14%)	
occurrences (all)	389	315	
Bronchitis			
subjects affected / exposed	188 / 1409 (13.34%)	195 / 1409 (13.84%)	
occurrences (all)	295	360	
Urinary tract infection			
subjects affected / exposed	200 / 1409 (14.19%)	193 / 1409 (13.70%)	
occurrences (all)	305	293	
Upper respiratory tract infection			
subjects affected / exposed	132 / 1409 (9.37%)	153 / 1409 (10.86%)	
occurrences (all)	209	266	

Gastroenteritis			
subjects affected / exposed	101 / 1409 (7.17%)	93 / 1409 (6.60%)	
occurrences (all)	115	116	
Pneumonia			
subjects affected / exposed	79 / 1409 (5.61%)	101 / 1409 (7.17%)	
occurrences (all)	101	116	
Respiratory tract infection			
subjects affected / exposed	70 / 1409 (4.97%)	76 / 1409 (5.39%)	
occurrences (all)	112	123	
Lower respiratory tract infection			
subjects affected / exposed	74 / 1409 (5.25%)	55 / 1409 (3.90%)	
occurrences (all)	135	105	
Influenza			
subjects affected / exposed	72 / 1409 (5.11%)	83 / 1409 (5.89%)	
occurrences (all)	97	111	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	122 / 1409 (8.66%)	140 / 1409 (9.94%)	
occurrences (all)	149	207	
Hyperphosphataemia			
subjects affected / exposed	136 / 1409 (9.65%)	142 / 1409 (10.08%)	
occurrences (all)	157	163	
Fluid overload			
subjects affected / exposed	115 / 1409 (8.16%)	130 / 1409 (9.23%)	
occurrences (all)	136	178	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 November 2008	As a precautionary measure and to ensure that MIRCERA would be supplied within specifications, the protocol was amended so that only pre-filled syringes with a shelf-life of at least 24 months were used, as vials have limited stability. Additional strengths of pre-filled syringes were added.
15 November 2011	Determination of cardiac markers at the time of suspected myocardial infarction was considered more appropriate than at pre-defined time points. The protocol was therefore amended to allow clinically meaningful assessment of this sampling while reducing the number of blood samples collected. Determination of coagulation parameters in case of hemorrhagic events was considered more appropriate than at pre-defined time points.
23 March 2015	Amendment to prolong the study by approximately 6 years (from the initial estimated duration of 4 years) because of a lower than anticipated event rate.

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.

The study was designed and powered to formally test only the primary composite endpoint only.

Notes: