



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
-----------------------	---------

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	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.

Arm title	Methoxy Polyethylene Glycol-Epoetin Beta
------------------	--

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	1412
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
-----------------------	-----------------------------------

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
-----------------------	--

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
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
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
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
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
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 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
-----------------	------------------------------------

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 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)
-----------------	---

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
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	20.1
--------------------	------

Reporting groups

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

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
-----------------------	-----------------------------------

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			
subjects affected / exposed	0 / 1409 (0.00%)	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	
Vlth 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	
Gastrooesophageal 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	
Calciophylaxis			
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: