

**Clinical trial results:**

**A multicenter, international, randomized, parallel group, double blind, placebo-controlled Cardiovascular Safety & Renal Microvascular outcome study with LINAgliptin, 5 mg once daily in patients with type 2 diabetes mellitus at high vascular risk. CARMELINA**

**Summary**

EudraCT number	2011-004148-23
Trial protocol	PT GB CZ NL HU ES PL BG HR DE
Global end of trial date	18 January 2018

**Results information**

Result version number	v1
This version publication date	02 February 2019
First version publication date	02 February 2019

**Trial information****Trial identification**

Sponsor protocol code	1218.22
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01897532
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure,, Boehringer Ingelheim, +001 8002430127, clintrriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim, +001 8002430127, clintrriage.rdg@boehringer-ingelheim.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	29 March 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 January 2018
Global end of trial reached?	Yes
Global end of trial date	18 January 2018
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective was to demonstrate non-inferiority (non-inferiority margin of 1.3 for the upper limit of the 95% confidence interval) of treatment with linagliptin in comparison to placebo (as add-on therapy to standard of care) with respect to time to first occurrence of any of the adjudicated components of the primary composite endpoint (i.e. cardiovascular [CV] death, non-fatal stroke or non-fatal myocardial infarction [MI]) in patients with type 2 diabetes mellitus (T2DM) at high risk of CV events.

If non-inferiority was demonstrated, then the primary composite endpoint was to be tested for superiority. The other objective, to assess the impact of treatment with respect to the composite renal endpoint (i.e. renal death, sustained end-stage renal disease [ESRD], sustained decrease in estimated glomerular filtration rate [eGFR]  $\geq 40\%$  from baseline), was to be investigated separately with a test on superiority.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 July 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1187
Country: Number of subjects enrolled	Brazil: 1658
Country: Number of subjects enrolled	Bulgaria: 165
Country: Number of subjects enrolled	Canada: 221
Country: Number of subjects enrolled	Chile: 156
Country: Number of subjects enrolled	China: 151
Country: Number of subjects enrolled	Colombia: 195
Country: Number of subjects enrolled	Croatia: 66
Country: Number of subjects enrolled	Czech Republic: 116
Country: Number of subjects enrolled	Germany: 37
Country: Number of subjects enrolled	Hungary: 231
Country: Number of subjects enrolled	Israel: 197
Country: Number of subjects enrolled	Japan: 101
Country: Number of subjects enrolled	Malaysia: 254

Country: Number of subjects enrolled	Mexico: 849
Country: Number of subjects enrolled	Netherlands: 82
Country: Number of subjects enrolled	Poland: 1040
Country: Number of subjects enrolled	Portugal: 90
Country: Number of subjects enrolled	Romania: 524
Country: Number of subjects enrolled	Russian Federation: 517
Country: Number of subjects enrolled	South Africa: 458
Country: Number of subjects enrolled	Korea, Republic of: 169
Country: Number of subjects enrolled	Spain: 221
Country: Number of subjects enrolled	Taiwan: 151
Country: Number of subjects enrolled	Ukraine: 878
Country: Number of subjects enrolled	United Kingdom: 216
Country: Number of subjects enrolled	United States: 2350
Worldwide total number of subjects	12280
EEA total number of subjects	2788

Notes:

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### 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)	5477
From 65 to 84 years	6634
85 years and over	169

## Subject disposition

### Recruitment

Recruitment details:

Prior to initiation of any trial-related procedure, all patients were informed about the trial verbally and in writing by the investigator. The patients signed and dated the informed consent before any study related procedures.

### Pre-assignment

Screening details:

All patients were screened for eligibility to participate in the trial. Subjects attended specialist sites which would then ensure that all subjects met all inclusion/exclusion criteria. Subjects were not to be entered to trial treatment if any one of the specific entry criteria were not met.

### Period 1

Period 1 title	On study period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Double blind trial

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Linagliptin

Arm description:

Patients were administered Linagliptin 5 milligram (mg) film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Five patients were randomised to the Linagliptin arm, however those five patients were not treated. Consequently, number of subjects that started (randomised) is 3499 but only 3494 reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Arm type	Experimental
Investigational medicinal product name	Linagliptin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered Linagliptin 5 milligram (mg) film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

<b>Arm title</b>	Placebo
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Arm description:

Patients were administered Placebo matching Linagliptin 5 mg film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Seven patients were randomised to the placebo arm, however those seven patients were not treated. Consequently, number of subjects that started (randomised) is 3492 but only 3485 reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Arm type	Placebo
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered Placebo matching Linagliptin 5 mg film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

<b>Number of subjects in period 1<sup>[1]</sup></b>	Linagliptin	Placebo
Started	3494	3485
Completed	3458	3430
Not completed	36	55
Patient lost to follow-up for MACE	36	55

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Baseline characteristics are based on patients who were treated after successfully completing the screening period and received at least one of the trial medication.

## Baseline characteristics

### Reporting groups

Reporting group title	Linagliptin
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Reporting group description:

Patients were administered Linagliptin 5 milligram (mg) film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Five patients were randomised to the Linagliptin arm, however those five patients were not treated. Consequently, number of subjects that started (randomised) is 3499 but only 3494 reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	Placebo
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Reporting group description:

Patients were administered Placebo matching Linagliptin 5 mg film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Seven patients were randomised to the placebo arm, however those seven patients were not treated. Consequently, number of subjects that started (randomised) is 3492 but only 3485 reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group values	Linagliptin	Placebo	Total
Number of subjects	3494	3485	6979
Age categorical			
Units: Subjects			

Age Continuous			
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Treated set (TS): All patients treated with at least one dose of trial medication. If no trial medication was taken at site during the visit, but the medication kit was dispensed to the patient and not all trial medication was returned, the patient was included in the TS.

Units: years			
arithmetic mean	66.1	65.6	
standard deviation	± 9.05	± 9.14	-

Sex: Female, Male			
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Treated set (TS): All patients treated with at least one dose of trial medication. If no trial medication was taken at site during the visit, but the medication kit was dispensed to the patient and not all trial medication was returned, the patient was included in the TS.

Units: Subjects			
Female	1346	1243	2589
Male	2148	2242	4390

Race (NIH/OMB)			
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Treated set (TS): All patients treated with at least one dose of trial medication. If no trial medication was taken at site during the visit, but the medication kit was dispensed to the patient and not all trial medication was returned, the patient was included in the TS.

Units: Subjects			
American Indian or Alaska Native	159	156	315
Asian	307	333	640
Native Hawaiian or Other Pacific Islander	7	10	17
Black or African American	194	217	411
White	2827	2769	5596
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Ethnicity (NIH/OMB)			
Treated set (TS): All patients treated with at least one dose of trial medication. If no trial medication was taken at site during the visit, but the medication kit was dispensed to the patient and not all trial medication was returned, the patient was included in the TS.			
Units: Subjects			
Hispanic or Latino	1227	1274	2501
Not Hispanic or Latino	2267	2211	4478
Unknown or Not Reported	0	0	0

## End points

### End points reporting groups

Reporting group title	Linagliptin
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Reporting group description:

Patients were administered Linagliptin 5 milligram (mg) film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Five patients were randomised to the Linagliptin arm, however those five patients were not treated. Consequently, number of subjects that started (randomised) is 3499 but only 3494 reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

Reporting group title	Placebo
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Reporting group description:

Patients were administered Placebo matching Linagliptin 5 mg film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Seven patients were randomised to the placebo arm, however those seven patients were not treated. Consequently, number of subjects that started (randomised) is 3492 but only 3485 reported to ensure consistent reporting with baseline characteristics that includes only treated patients.

### **Primary: Time to the first occurrence of any of the following adjudication-confirmed components of the primary composite endpoint 3-point major adverse cardiovascular (CV) events (3-point MACE): CV death, non-fatal myocardial infarction (MI) or non-fatal stroke.**

End point title	Time to the first occurrence of any of the following adjudication-confirmed components of the primary composite endpoint 3-point major adverse cardiovascular (CV) events (3-point MACE): CV death, non-fatal myocardial infarction (MI) or non-fatal stroke.
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End point description:

Time to the first occurrence of any of the following adjudication-confirmed components of the primary composite endpoint 3-point major adverse cardiovascular (CV) events (3-point MACE): CV death, non-fatal myocardial infarction (MI) or non-fatal stroke. The percentage of observed patients with first occurrence of any of the following adjudication-confirmed components of the primary composite endpoint (3-point MACE) was reported.

End point type	Primary
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End point timeframe:

From randomization to individual end of observation; up to 4.3 years

<b>End point values</b>	Linagliptin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494 <sup>[1]</sup>	3485 <sup>[2]</sup>		
Units: percentage of participants				
number (not applicable)	12.4	12.1		

Notes:

[1] - TS

[2] - TS

### Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis 1
Statistical analysis description:	
Cox proportional hazard regression model was performed to compare the effect of linagliptin versus placebo. Model included randomised treatment and geographical region as factors. Breslow's method was used for dealing with ties. First hypothesis (non-inferiority of the primary endpoint) was to be tested at the one-sided alpha-level of 2.5%. In case of significance the next set of hypotheses (two separate hypothesis tests) were to be tested with a sequentially rejective multiple test procedure.	
Comparison groups	Linagliptin v Placebo
Number of subjects included in analysis	6979
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[3]</sup>
P-value	= 0.0002 <sup>[4]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.17

Notes:

[3] - The non-inferiority margin was chosen as 1.3 (FDA Guidance for Industry - Diabetes Mellitus - Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes).

[4] - p-value for Hazard ratio (HR)  $\geq 1.3$  (1-sided).

Based on a Cox regression model with terms for treatment group and region.

<b>Statistical analysis title</b>	Statistical Analysis 2
Statistical analysis description:	
Cox proportional hazard regression model was performed to compare the effect of linagliptin versus placebo. Model included randomised treatment and geographical region as factors. Breslow's method was used for dealing with ties. First hypothesis (non-inferiority of the primary endpoint) was to be tested at the one-sided alpha-level of 2.5%. In case of significance the next set of hypotheses (two separate hypothesis tests) were to be tested with a sequentially rejective multiple test procedure.	
Comparison groups	Linagliptin v Placebo
Number of subjects included in analysis	6979
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.6301 <sup>[5]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.17

Notes:

[5] - p-value for HR  $\geq 1.0$  (1-sided).

Based on a Cox regression model with terms for treatment group and region.

**Secondary: Time to the first occurrence of any of the following adjudication-confirmed components: renal death, sustained End Stage Renal Disease (ESRD), or sustained decrease of 40% or more in Estimated Glomerular Filtration Rate (eGFR).**

End point title	Time to the first occurrence of any of the following adjudication-confirmed components: renal death, sustained
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End Stage Renal Disease (ESRD), or sustained decrease of 40% or more in Estimated Glomerular Filtration Rate (eGFR).

End point description:

Time to the first occurrence of any of the following adjudication-confirmed components: renal death, sustained ESRD, or sustained decrease of 40% or more in eGFR. The percentage of observed patients with first occurrence of any of the following adjudication-confirmed components: renal death, sustained ESRD, or sustained decrease of 40% or more in eGFR was reported.

End point type Secondary

End point timeframe:

From randomization to individual end of observation; up to 4.3 years

End point values	Linagliptin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494 <sup>[6]</sup>	3485 <sup>[7]</sup>		
Units: percentage of participants				
number (not applicable)	9.4	8.8		

Notes:

[6] - TS

[7] - TS

### Statistical analyses

Statistical analysis title Statistical Analysis 1

Statistical analysis description:

Cox proportional hazard regression model was performed to compare the effect of linagliptin versus placebo. Model included randomised treatment and geographical region as factors. Breslow's method was used for dealing with ties. First hypothesis (non-inferiority of the primary endpoint) was to be tested at the one-sided alpha-level of 2.5%. In case of significance the next set of hypotheses (two separate hypothesis tests) were to be tested with a sequentially rejective multiple test procedure.

Comparison groups	Linagliptin v Placebo
Number of subjects included in analysis	6979
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6918 <sup>[8]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.22

Notes:

[8] - p-value for HR  $\geq 1.0$  (1-sided).

Based on a Cox regression model with terms for treatment group and region.

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events with an onset after the first dose of trial medication up to a period of 7 days after the last permanent study drug stop; up to 4.3 years

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Patients were administered Placebo matching Linagliptin 5 mg film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

Reporting group title	Linagliptin
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Reporting group description:

Patients were administered Linagliptin 5 milligram (mg) film-coated tablet orally once daily. At Visit 2, patients received one treatment box sufficient for 12 weeks treatment (plus 1 week reserve). At Visit 3 (until trial end) patients received 2 medication boxes sufficient for 24 weeks treatment (plus 2 weeks reserve).

<b>Serious adverse events</b>	Placebo	Linagliptin	
Total subjects affected by serious adverse events			
subjects affected / exposed	1343 / 3485 (38.54%)	1293 / 3494 (37.01%)	
number of deaths (all causes)	373	367	
number of deaths resulting from adverse events	10	21	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute monocytic leukaemia			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute promyelocytic leukaemia			

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma gastric		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	4 / 3485 (0.11%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Basal cell carcinoma		
subjects affected / exposed	14 / 3485 (0.40%)	14 / 3494 (0.40%)
occurrences causally related to treatment / all	0 / 15	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma of skin		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign breast neoplasm		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ovarian tumour		

subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder cancer</b>		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Bladder neoplasm</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder transitional cell carcinoma</b>		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bowen's disease</b>		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain neoplasm</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast cancer</b>		
subjects affected / exposed	4 / 3485 (0.11%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Bronchial carcinoma</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cancer pain</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac myxoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac neoplasm unspecified		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
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	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall tumour		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		

subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	7 / 3485 (0.20%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Colon neoplasm		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diffuse large b-cell lymphoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric adenoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal cancer metastatic		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal neoplasm		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Hepatic neoplasm		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hodgkin's disease		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		

subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyosarcoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lip neoplasm malignant stage unspecified		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Lung adenocarcinoma stage 0		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		

subjects affected / exposed	5 / 3485 (0.14%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 5
<b>Lymphoma</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Malignant anorectal neoplasm</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant melanoma</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Malignant melanoma in situ</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malignant pleural effusion</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Mediastinum neoplasm</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningioma</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to bone</b>		

subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to liver		
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to lung		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
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 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mucinous cystadenocarcinoma of pancreas		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Myeloproliferative neoplasm		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Naevoid melanoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
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	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal carcinoma recurrent		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary renal cell carcinoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Penile squamous cell carcinoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	8 / 3485 (0.23%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	1 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer metastatic		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cancer		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cell carcinoma		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal neoplasm</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Schwannoma</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sebaceous adenoma</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Small cell lung cancer</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Squamous cell carcinoma of lung</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Squamous cell carcinoma of skin</b>		
subjects affected / exposed	9 / 3485 (0.26%)	8 / 3494 (0.23%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Testis cancer</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tongue cancer recurrent</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour of ampulla of vater			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
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	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Accelerated hypertension			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiopathy			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	1 / 3485 (0.03%)	4 / 3494 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic aneurysm rupture			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic stenosis			
subjects affected / exposed	5 / 3485 (0.14%)	8 / 3494 (0.23%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial insufficiency			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial rupture			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			

subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Arteriovenous fistula		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure inadequately controlled		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Deep vein thrombosis		
subjects affected / exposed	14 / 3485 (0.40%)	12 / 3494 (0.34%)
occurrences causally related to treatment / all	0 / 15	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic macroangiopathy		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (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	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Distributive shock		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Dry gangrene		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Embolism</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Embolism arterial</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Embolism venous</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Extremity necrosis</b>		
subjects affected / exposed	9 / 3485 (0.26%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Femoral artery aneurysm</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematoma</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertension</b>		
subjects affected / exposed	18 / 3485 (0.52%)	32 / 3494 (0.92%)
occurrences causally related to treatment / all	0 / 19	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Hypertensive crisis</b>		

subjects affected / exposed	20 / 3485 (0.57%)	16 / 3494 (0.46%)
occurrences causally related to treatment / all	0 / 22	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	7 / 3485 (0.20%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 3485 (0.03%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Iliac artery occlusion		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypertension		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	0 / 3485 (0.00%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		

subjects affected / exposed	17 / 3485 (0.49%)	18 / 3494 (0.52%)
occurrences causally related to treatment / all	1 / 17	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	12 / 3485 (0.34%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 13	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	11 / 3485 (0.32%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	7 / 3485 (0.20%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic hypertension		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular insufficiency		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vein rupture		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Coronary revascularisation			
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral endarterectomy			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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			
Application site haemorrhage			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	8 / 3485 (0.23%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	1 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	5 / 3485 (0.14%)	7 / 3494 (0.20%)	
occurrences causally related to treatment / all	1 / 5	1 / 7	
deaths causally related to treatment / all	1 / 5	1 / 7	

Catheter site haemorrhage			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic fatigue syndrome			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	23 / 3485 (0.66%)	16 / 3494 (0.46%)	
occurrences causally related to treatment / all	0 / 23	0 / 16	
deaths causally related to treatment / all	0 / 23	0 / 16	
Feeling abnormal			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	1 / 1	0 / 3
deaths causally related to treatment / all	1 / 1	0 / 0
Impaired healing		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site haematoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site joint inflammation		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Necrobiosis		

subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	15 / 3485 (0.43%)	15 / 3494 (0.43%)
occurrences causally related to treatment / all	0 / 16	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	2 / 3485 (0.06%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated hernia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1
Sudden death		
subjects affected / exposed	20 / 3485 (0.57%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 20	0 / 10
deaths causally related to treatment / all	0 / 20	0 / 10
Systemic inflammatory response syndrome		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
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	1 / 3485 (0.03%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
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	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overlap syndrome			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Homicide			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Limb prosthesis user			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
Acquired hydrocele			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired phimosis			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	8 / 3485 (0.23%)	4 / 3494 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polyp			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hypertrophy			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			

subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal leukoplakia			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	15 / 3485 (0.43%)	13 / 3494 (0.37%)	
occurrences causally related to treatment / all	0 / 18	1 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	11 / 3485 (0.32%)	9 / 3494 (0.26%)	
occurrences causally related to treatment / all	0 / 11	1 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asphyxia			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aspiration			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			

subjects affected / exposed	3 / 3485 (0.09%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atelectasis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis chronic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchospasm</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic obstructive pulmonary disease</b>		
subjects affected / exposed	28 / 3485 (0.80%)	21 / 3494 (0.60%)
occurrences causally related to treatment / all	0 / 38	0 / 28
deaths causally related to treatment / all	0 / 3	0 / 0
<b>Chronic respiratory failure</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cough</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspnoea</b>		
subjects affected / exposed	16 / 3485 (0.46%)	16 / 3494 (0.46%)
occurrences causally related to treatment / all	0 / 18	1 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Dyspnoea exertional</b>		

subjects affected / exposed	5 / 3485 (0.14%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Emphysema</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eosinophilic pneumonia</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epistaxis</b>		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemoptysis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemothorax</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoxia</b>		
subjects affected / exposed	1 / 3485 (0.03%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Interstitial lung disease</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laryngeal oedema</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal mass		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mendelson's syndrome		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraneoplastic pleural effusion		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	11 / 3485 (0.32%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	1 / 11	0 / 6
deaths causally related to treatment / all	1 / 1	0 / 0
Pleural thickening		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonitis		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Portopulmonary hypertension		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	12 / 3485 (0.34%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 2
Pulmonary fibrosis		
subjects affected / exposed	5 / 3485 (0.14%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	14 / 3485 (0.40%)	12 / 3494 (0.34%)
occurrences causally related to treatment / all	0 / 14	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		

subjects affected / exposed	13 / 3485 (0.37%)	16 / 3494 (0.46%)
occurrences causally related to treatment / all	1 / 13	0 / 17
deaths causally related to treatment / all	1 / 2	0 / 1
Respiratory arrest		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Respiratory failure		
subjects affected / exposed	14 / 3485 (0.40%)	13 / 3494 (0.37%)
occurrences causally related to treatment / all	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 2	0 / 5
Restrictive pulmonary disease		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus polyp		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord cyst		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord disorder		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affect lability			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Confusional state			

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Delirium</b>		
subjects affected / exposed	4 / 3485 (0.11%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Depression</b>		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Drug use disorder</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hallucination, visual</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Insomnia</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Irritability</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Major depression</b>		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental status changes</b>		

subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mood disorder due to a general medical condition</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychotic disorder</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Suicidal ideation</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Product issues</b>			
<b>Device failure</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device malfunction</b>			
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatobiliary disorders</b>			
<b>Autoimmune hepatitis</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bile duct obstruction</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bile duct stone			
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyspepsia			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract disorder			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	3 / 3485 (0.09%)	7 / 3494 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	7 / 3485 (0.20%)	10 / 3494 (0.29%)	
occurrences causally related to treatment / all	0 / 7	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholelithiasis</b>		
subjects affected / exposed	9 / 3485 (0.26%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	1 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cirrhosis alcoholic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic cirrhosis</b>		
subjects affected / exposed	2 / 3485 (0.06%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic failure</b>		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Hepatic steatosis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic hepatitis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Jaundice</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Portal hypertension</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration bronchial			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			

subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Catheterisation cardiac		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Creatinine renal clearance decreased		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Echocardiogram		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram qt prolonged		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram t wave inversion		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerular filtration rate decreased		
subjects affected / exposed	30 / 3485 (0.86%)	36 / 3494 (1.03%)
occurrences causally related to treatment / all	0 / 33	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosylated haemoglobin increased		

subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza a virus test positive		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac pressure increased		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipase increased		
subjects affected / exposed	5 / 3485 (0.14%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	2 / 5	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test abnormal		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test increased		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic specific antigen increased		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcus test positive		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine output decreased			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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			
Animal bite			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic complication			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
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 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	0 / 3485 (0.00%)	5 / 3494 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site complication			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula thrombosis			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone contusion</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Back injury</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain contusion</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carbon monoxide poisoning</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Burns second degree</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chest injury</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervical vertebral fracture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Contusion</b>		

subjects affected / exposed	3 / 3485 (0.09%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Colon injury		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Endotracheal intubation complication		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	25 / 3485 (0.72%)	19 / 3494 (0.54%)
occurrences causally related to treatment / all	1 / 25	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		

subjects affected / exposed	6 / 3485 (0.17%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fibula fracture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Foot fracture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fracture displacement</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hand fracture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Head injury</b>		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Heart injury</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hip fracture</b>		
subjects affected / exposed	7 / 3485 (0.20%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Humerus fracture</b>		

subjects affected / exposed	3 / 3485 (0.09%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyphaema		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incomplete spinal fusion		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb crushing injury</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb injury</b>		
subjects affected / exposed	5 / 3485 (0.14%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower limb fracture</b>		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar vertebral fracture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple injuries</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle injury</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle strain</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Overdose</b>		

subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Periprocedural myocardial infarction		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal dialysis complication		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
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 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative delirium		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory distress		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypotension		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural intestinal perforation		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	1 / 3485 (0.03%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	7 / 3485 (0.20%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Scar		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skeletal injury</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Skull fractured base</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal compression fracture</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal fracture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic rupture</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sternal fracture</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stoma site polyp</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stomal hernia</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Subdural haematoma		
subjects affected / exposed	1 / 3485 (0.03%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Subdural haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	3 / 3485 (0.09%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic liver injury		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vith nerve injury		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Congenital, familial and genetic disorders</b>			
<b>Accessory spleen</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Atrial septal defect</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cystic lymphangioma</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dermoid cyst</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal arteriovenous malformation</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypertrophic cardiomyopathy</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Keratosis follicular</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Myocardial bridging</b>			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
Acute left ventricular failure			
subjects affected / exposed	8 / 3485 (0.23%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 10	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	18 / 3485 (0.52%)	12 / 3494 (0.34%)	
occurrences causally related to treatment / all	2 / 19	0 / 17	
deaths causally related to treatment / all	0 / 2	0 / 1	
Acute myocardial infarction			
subjects affected / exposed	59 / 3485 (1.69%)	78 / 3494 (2.23%)	
occurrences causally related to treatment / all	5 / 70	6 / 101	
deaths causally related to treatment / all	1 / 10	4 / 17	
Adams-stokes syndrome			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	25 / 3485 (0.72%)	42 / 3494 (1.20%)	
occurrences causally related to treatment / all	0 / 34	1 / 51	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	70 / 3485 (2.01%)	77 / 3494 (2.20%)	
occurrences causally related to treatment / all	1 / 77	6 / 84	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Arrhythmia supraventricular		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	26 / 3485 (0.75%)	34 / 3494 (0.97%)
occurrences causally related to treatment / all	0 / 28	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriosclerosis coronary artery		
subjects affected / exposed	6 / 3485 (0.17%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Atrial flutter		
subjects affected / exposed	11 / 3485 (0.32%)	13 / 3494 (0.37%)
occurrences causally related to treatment / all	0 / 18	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	5 / 3485 (0.14%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	10 / 3485 (0.29%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradycardia</b>		
subjects affected / exposed	6 / 3485 (0.17%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block second degree</b>		
subjects affected / exposed	4 / 3485 (0.11%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bundle branch block left</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac disorder</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Cardiac arrest</b>		
subjects affected / exposed	17 / 3485 (0.49%)	25 / 3494 (0.72%)
occurrences causally related to treatment / all	1 / 17	0 / 25
deaths causally related to treatment / all	1 / 15	0 / 23
<b>Cardiac failure chronic</b>		
subjects affected / exposed	20 / 3485 (0.57%)	24 / 3494 (0.69%)
occurrences causally related to treatment / all	0 / 28	0 / 30
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Cardiac failure acute</b>		
subjects affected / exposed	7 / 3485 (0.20%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 2	0 / 2
<b>Cardiac failure</b>		

subjects affected / exposed	104 / 3485 (2.98%)	104 / 3494 (2.98%)
occurrences causally related to treatment / all	3 / 141	3 / 148
deaths causally related to treatment / all	1 / 10	3 / 14
Cardiac tamponade		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	98 / 3485 (2.81%)	77 / 3494 (2.20%)
occurrences causally related to treatment / all	5 / 153	10 / 102
deaths causally related to treatment / all	0 / 3	1 / 6
Cardio-respiratory arrest		
subjects affected / exposed	8 / 3485 (0.23%)	8 / 3494 (0.23%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 7	0 / 7
Cardiogenic shock		
subjects affected / exposed	12 / 3485 (0.34%)	8 / 3494 (0.23%)
occurrences causally related to treatment / all	1 / 12	3 / 8
deaths causally related to treatment / all	1 / 12	2 / 6
Cardiomegaly		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiomyopathy		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiomyopathy acute		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		

subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 3
Cardiorenal syndrome		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 1	1 / 2
Chordae tendinae rupture		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic left ventricular failure		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Conduction disorder		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	21 / 3485 (0.60%)	26 / 3494 (0.74%)
occurrences causally related to treatment / all	1 / 23	3 / 27
deaths causally related to treatment / all	0 / 2	0 / 1
Coronary artery occlusion		

subjects affected / exposed	3 / 3485 (0.09%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	8 / 3485 (0.23%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	1 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cyanosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Degenerative mitral valve disease		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	3 / 3485 (0.09%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		

subjects affected / exposed	12 / 3485 (0.34%)	13 / 3494 (0.37%)
occurrences causally related to treatment / all	0 / 13	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Mitral valve disease</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve incompetence</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve stenosis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial fibrosis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Myocardial infarction</b>		
subjects affected / exposed	54 / 3485 (1.55%)	47 / 3494 (1.35%)
occurrences causally related to treatment / all	3 / 64	1 / 49
deaths causally related to treatment / all	0 / 8	1 / 14
<b>Myocardial ischaemia</b>		
subjects affected / exposed	12 / 3485 (0.34%)	20 / 3494 (0.57%)
occurrences causally related to treatment / all	1 / 14	1 / 20
deaths causally related to treatment / all	0 / 1	0 / 3
<b>Myocardial necrosis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocarditis</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paroxysmal atrioventricular block		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pericarditis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis constrictive		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Silent myocardial infarction		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		

subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	4 / 3485 (0.11%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic dysfunction		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular arrhythmia</b>			
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Ventricular extrasystoles</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular fibrillation</b>			
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Ventricular tachycardia</b>			
subjects affected / exposed	3 / 3485 (0.09%)	3 / 3494 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Nervous system disorders</b>			
<b>Altered state of consciousness</b>			
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Basal ganglia infarction</b>			
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Brain injury</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Brain oedema</b>			

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Brain stem infarction</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid arteriosclerosis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery dissection</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery occlusion</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery stenosis</b>		
subjects affected / exposed	6 / 3485 (0.17%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid sinus syndrome</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carpal tunnel syndrome</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Central nervous system lesion</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebral ischaemia		
subjects affected / exposed	4 / 3485 (0.11%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	8 / 3485 (0.23%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral small vessel ischaemic disease		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrospinal fluid leakage		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular disorder		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		

subjects affected / exposed	12 / 3485 (0.34%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 13	1 / 11
deaths causally related to treatment / all	0 / 3	1 / 4
Cervicobrachial syndrome		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Complex regional pain syndrome		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia with lewy bodies		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	6 / 3485 (0.17%)	8 / 3494 (0.23%)
occurrences causally related to treatment / all	1 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic coma		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 1	1 / 2
Diabetic neuropathy		

subjects affected / exposed	5 / 3485 (0.14%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dyskinesia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	0 / 3485 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial nerve disorder		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic stroke</b>		
subjects affected / exposed	8 / 3485 (0.23%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 5	1 / 5
<b>Haemorrhage intracranial</b>		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 1	1 / 3
<b>Headache</b>		
subjects affected / exposed	4 / 3485 (0.11%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hemiparesis</b>		
subjects affected / exposed	4 / 3485 (0.11%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic encephalopathy</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hemiplegia</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive encephalopathy</b>		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoglycaemic coma</b>		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoxic-ischaemic encephalopathy</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Incoherent</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intracranial pressure increased</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intracranial aneurysm</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intraventricular haemorrhage</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic cerebral infarction</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Ischaemic stroke</b>		
subjects affected / exposed	49 / 3485 (1.41%)	61 / 3494 (1.75%)
occurrences causally related to treatment / all	2 / 53	5 / 63
deaths causally related to treatment / all	1 / 4	2 / 9
<b>Lacunar infarction</b>		

subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuritis cranial		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroglycopenia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke seizure		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	7 / 3485 (0.20%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	6 / 3485 (0.17%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal claudication		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal epidural haematoma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		

subjects affected / exposed	25 / 3485 (0.72%)	15 / 3494 (0.43%)
occurrences causally related to treatment / all	1 / 28	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic stroke		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Transient ischaemic attack		
subjects affected / exposed	9 / 3485 (0.26%)	27 / 3494 (0.77%)
occurrences causally related to treatment / all	0 / 11	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uraemic encephalopathy		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular headache		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vith nerve paralysis		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke's encephalopathy			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	17 / 3485 (0.49%)	19 / 3494 (0.54%)	
occurrences causally related to treatment / all	0 / 17	0 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia macrocytic			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of malignant disease			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilia			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
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 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (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	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Conductive deafness			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness bilateral			
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	3 / 3485 (0.09%)	4 / 3494 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Acquired corneal dystrophy			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis fugax			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blindness unilateral		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract		
subjects affected / exposed	13 / 3485 (0.37%)	11 / 3494 (0.31%)
occurrences causally related to treatment / all	0 / 17	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract cortical		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal decompensation		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystoid macular oedema		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinal oedema		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		

subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dry age-related macular degeneration		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	9 / 3485 (0.26%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hyalosis asteroid		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Macular degeneration		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		
subjects affected / exposed	2 / 3485 (0.06%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	1 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neovascular age-related macular degeneration		

subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery embolism		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal degeneration		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	5 / 3485 (0.14%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		

subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Retinopathy</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ulcerative keratitis</b>			
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Uveitis</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vitreous haematoma</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vitreous haemorrhage</b>			
subjects affected / exposed	5 / 3485 (0.14%)	6 / 3494 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal disorders</b>			
<b>Abdominal adhesions</b>			
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal hernia</b>			
subjects affected / exposed	5 / 3485 (0.14%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal hernia obstructive</b>			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain		
subjects affected / exposed	5 / 3485 (0.14%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Abdominal pain upper		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal tenderness		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal polyp		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	1 / 3485 (0.03%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Constipation		
subjects affected / exposed	4 / 3485 (0.11%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	2 / 3485 (0.06%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal vascular ectasia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis haemorrhagic		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		

subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
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	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric antral vascular ectasia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		

subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	8 / 3485 (0.23%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	1 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal haemorrhage		

subjects affected / exposed	11 / 3485 (0.32%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal perforation		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haematochezia		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	5 / 3485 (0.14%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	3 / 3485 (0.09%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal perforation		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal obstruction		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	3 / 3485 (0.09%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	3 / 3485 (0.09%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lip ulceration		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	0 / 3485 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mesenteric haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema mouth		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic failure		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	3 / 3485 (0.09%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	2 / 3	3 / 6
deaths causally related to treatment / all	0 / 0	1 / 1
Pancreatitis acute		

subjects affected / exposed	3 / 3485 (0.09%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	1 / 3	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pancreatitis chronic</b>		
subjects affected / exposed	6 / 3485 (0.17%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	2 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic ulcer</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritoneal adhesions</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal haemorrhage</b>		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal polyp</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal fibrosis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Small intestinal obstruction</b>		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Strangulated umbilical hernia</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue oedema			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	5 / 3485 (0.14%)	8 / 3494 (0.23%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vomiting			
subjects affected / exposed	3 / 3485 (0.09%)	6 / 3494 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting projectile			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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			
Angioedema			
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis bullous		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis exfoliative generalised		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	24 / 3485 (0.69%)	21 / 3494 (0.60%)
occurrences causally related to treatment / all	0 / 28	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Ecchymosis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ichthyosis acquired		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic skin ulcer		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Necrobiosis lipidica diabetorum		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurodermatitis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pemphigoid</b>		
subjects affected / exposed	0 / 3485 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pruritus</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rash</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rash maculo-papular</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin necrosis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin ulcer</b>		
subjects affected / exposed	10 / 3485 (0.29%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin ulcer haemorrhage</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Stasis dermatitis</b>			
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Swelling face</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Toxic epidermal necrolysis</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Renal and urinary disorders</b>			
<b>Acute kidney injury</b>			
subjects affected / exposed	100 / 3485 (2.87%)	96 / 3494 (2.75%)	
occurrences causally related to treatment / all	1 / 111	4 / 109	
deaths causally related to treatment / all	0 / 1	0 / 2	
<b>Acute prerenal failure</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anuria</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Azotaemia</b>			
subjects affected / exposed	6 / 3485 (0.17%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder prolapse</b>			

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Calculus bladder</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic kidney disease</b>		
subjects affected / exposed	32 / 3485 (0.92%)	49 / 3494 (1.40%)
occurrences causally related to treatment / all	1 / 35	2 / 56
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Diabetic nephropathy</b>		
subjects affected / exposed	7 / 3485 (0.20%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Dysuria</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>End stage renal disease</b>		
subjects affected / exposed	45 / 3485 (1.29%)	38 / 3494 (1.09%)
occurrences causally related to treatment / all	0 / 49	3 / 39
deaths causally related to treatment / all	0 / 2	1 / 3
<b>Glomerulonephritis membranous</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematuria</b>		
subjects affected / exposed	4 / 3485 (0.11%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydronephrosis</b>		

subjects affected / exposed	1 / 3485 (0.03%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive nephropathy</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mesangioproliferative glomerulonephritis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrolithiasis</b>		
subjects affected / exposed	7 / 3485 (0.20%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 7	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephropathy</b>		
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephropathy toxic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrotic syndrome</b>		
subjects affected / exposed	2 / 3485 (0.06%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	1 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oliguria</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Proteinuria</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal artery stenosis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal colic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal disorder</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal failure</b>		
subjects affected / exposed	31 / 3485 (0.89%)	32 / 3494 (0.92%)
occurrences causally related to treatment / all	2 / 33	2 / 32
deaths causally related to treatment / all	0 / 1	0 / 4
<b>Renal impairment</b>		
subjects affected / exposed	27 / 3485 (0.77%)	24 / 3494 (0.69%)
occurrences causally related to treatment / all	1 / 29	2 / 26
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Renal mass</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal pain</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal tubular necrosis</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	1 / 3485 (0.03%)	4 / 3494 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral haemorrhage			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	6 / 3485 (0.17%)	5 / 3494 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal mass			

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Goitre</b>			
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperthyroidism</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypothyroidism</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thyroid mass</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Ankylosing spondylitis</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthralgia</b>			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis</b>			
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis reactive</b>			

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bone pain		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic arthropathy		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc disorder</b>		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc protrusion</b>		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint range of motion decreased</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb discomfort</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar spinal stenosis</b>		
subjects affected / exposed	4 / 3485 (0.11%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle haemorrhage</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle spasms</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal chest pain</b>		

subjects affected / exposed	6 / 3485 (0.17%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal pain</b>		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myopathy</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myopathy toxic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neck pain</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuropathic arthropathy</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteitis</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoarthritis</b>		
subjects affected / exposed	17 / 3485 (0.49%)	15 / 3494 (0.43%)
occurrences causally related to treatment / all	0 / 18	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondrosis</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain in extremity</b>		
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pathological fracture</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periostitis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Plantar fasciitis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polymyalgia rheumatica</b>		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhabdomyolysis</b>		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rheumatoid arthritis</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic lupus erythematosus		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral osteophyte		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal sepsis</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Abdominal wall abscess</b>			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abscess limb</b>			
subjects affected / exposed	4 / 3485 (0.11%)	2 / 3494 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anal abscess</b>			
subjects affected / exposed	4 / 3485 (0.11%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Appendicitis</b>			
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis bacterial</b>			
subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bacterial infection</b>			

subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial pyelonephritis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial sepsis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Blebitis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	17 / 3485 (0.49%)	8 / 3494 (0.23%)
occurrences causally related to treatment / all	0 / 17	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bursitis infective</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carbuncle</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Catheter site infection</b>		

subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	38 / 3485 (1.09%)	22 / 3494 (0.63%)
occurrences causally related to treatment / all	0 / 42	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Chikungunya virus infection		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium colitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus infection		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	2 / 3485 (0.06%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic foot infection		
subjects affected / exposed	6 / 3485 (0.17%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	2 / 3485 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		

subjects affected / exposed	2 / 3485 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Endocarditis bacterial</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Enteritis infectious</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epididymitis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erysipelas</b>		
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia bacteraemia</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia sepsis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia urinary tract infection</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fungal peritonitis</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	14 / 3485 (0.40%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	9 / 3485 (0.26%)	11 / 3494 (0.31%)
occurrences causally related to treatment / all	1 / 9	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis shigella		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal bacterial infection		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal viral infection		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Graft infection</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Groin abscess</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>H1n1 influenza</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatitis c</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatitis infectious mononucleosis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes zoster</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Histoplasmosis cutaneous</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Histoplasmosis disseminated</b>		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (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 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	6 / 3485 (0.17%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	2 / 3485 (0.06%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site abscess		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal sepsis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella infection		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leptospirosis		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	7 / 3485 (0.20%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Lyme disease		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site cellulitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis viral		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myiasis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mycoplasma infection</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Necrotising fasciitis</b>		
subjects affected / exposed	3 / 3485 (0.09%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Neutropenic sepsis</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nosocomial infection</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oral candidiasis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orchitis</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis</b>		

subjects affected / exposed	14 / 3485 (0.40%)	11 / 3494 (0.31%)
occurrences causally related to treatment / all	0 / 15	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis chronic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis viral</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis externa</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic abscess</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paronychia</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periodontitis</b>		
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Perineal abscess</b>		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	4 / 3485 (0.11%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Peritonitis bacterial		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	121 / 3485 (3.47%)	99 / 3494 (2.83%)
occurrences causally related to treatment / all	1 / 139	0 / 114
deaths causally related to treatment / all	0 / 10	0 / 5
Pneumonia bacterial		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia chlamydial		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	3 / 3485 (0.09%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	2 / 3485 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonas infection		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulpitis dental		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		

subjects affected / exposed	3 / 3485 (0.09%)	14 / 3494 (0.40%)
occurrences causally related to treatment / all	0 / 3	0 / 18
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Pyelonephritis acute</b>		
subjects affected / exposed	3 / 3485 (0.09%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis chronic</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal abscess</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory tract infection</b>		
subjects affected / exposed	7 / 3485 (0.20%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Respiratory tract infection viral</b>		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal abscess</b>		
subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrub typhus</b>		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		

subjects affected / exposed	33 / 3485 (0.95%)	18 / 3494 (0.52%)
occurrences causally related to treatment / all	0 / 34	1 / 18
deaths causally related to treatment / all	0 / 11	0 / 2
Septic shock		
subjects affected / exposed	12 / 3485 (0.34%)	13 / 3494 (0.37%)
occurrences causally related to treatment / all	1 / 12	1 / 13
deaths causally related to treatment / all	0 / 8	0 / 8
Sialoadenitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
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 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord abscess		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	4 / 3485 (0.11%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic infection		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth infection		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	2 / 3485 (0.06%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	41 / 3485 (1.18%)	30 / 3494 (0.86%)	
occurrences causally related to treatment / all	0 / 44	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection fungal			
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	7 / 3485 (0.20%)	5 / 3494 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Viraemia			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral tonsillitis			
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 3485 (0.06%)	0 / 3494 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Abnormal loss of weight			

subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acquired mixed hyperlipidaemia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Decreased appetite		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dehydration		
subjects affected / exposed	6 / 3485 (0.17%)	11 / 3494 (0.31%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	7 / 3485 (0.20%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetes mellitus inadequate control		
subjects affected / exposed	10 / 3485 (0.29%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 10	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes with hyperosmolarity		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	4 / 3485 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		

subjects affected / exposed	5 / 3485 (0.14%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	3 / 3485 (0.09%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to thrive		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid imbalance		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	11 / 3485 (0.32%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	1 / 14	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 3485 (0.03%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		

subjects affected / exposed	22 / 3485 (0.63%)	12 / 3494 (0.34%)
occurrences causally related to treatment / all	2 / 24	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	19 / 3485 (0.55%)	16 / 3494 (0.46%)
occurrences causally related to treatment / all	0 / 21	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 1
Hyperlipasaemia		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypernatraemia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperphosphataemia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperuricaemia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		

subjects affected / exposed	0 / 3485 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	38 / 3485 (1.09%)	28 / 3494 (0.80%)
occurrences causally related to treatment / all	20 / 47	15 / 40
deaths causally related to treatment / all	0 / 0	0 / 1
Hypokalaemia		
subjects affected / exposed	1 / 3485 (0.03%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	5 / 3485 (0.14%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophagia		
subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	3 / 3485 (0.09%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lactic acidosis		
subjects affected / exposed	1 / 3485 (0.03%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	1 / 3485 (0.03%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 4
Obesity		

subjects affected / exposed	1 / 3485 (0.03%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	0 / 3485 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vitamin d deficiency		
subjects affected / exposed	0 / 3485 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Placebo	Linagliptin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1422 / 3485 (40.80%)	1434 / 3494 (41.04%)	
Investigations			
Glomerular filtration rate decreased			
subjects affected / exposed	200 / 3485 (5.74%)	202 / 3494 (5.78%)	
occurrences (all)	251	248	
Vascular disorders			
Hypertension			
subjects affected / exposed	232 / 3485 (6.66%)	216 / 3494 (6.18%)	
occurrences (all)	273	255	
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	162 / 3485 (4.65%)	196 / 3494 (5.61%)	
occurrences (all)	218	267	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	240 / 3485 (6.89%)	208 / 3494 (5.95%)	
occurrences (all)	917	975	
Hypoglycaemia			

subjects affected / exposed	1003 / 3485 (28.78%)	1022 / 3494 (29.25%)	
occurrences (all)	7206	6434	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 October 2013	Renal composite 2 endpoint (renal death, sustained ESRD, sustained decrease of 40% or more in eGFR) added as tertiary endpoint (This tertiary endpoint was then with amendment No.2 (22 Nov 2016) elevated to become key secondary endpoint)
22 November 2016	<ul style="list-style-type: none"><li>- Number of patients with primary endpoint events decreased from 625 to 611 and estimated treatment period increased from 48 to 54 months. Since the interim analysis for efficacy was removed from the protocol, the required number of patients with primary endpoint to achieve a power of 90% for non-inferiority is reduced from 625 to 611. The estimated trial duration increased slightly due to the change of the primary endpoint while ensuring a sufficiently long drug exposure for the last recruited patients.</li><li>- The primary endpoint changed from 4-point MACE to 3-point MACE in line with advice by the independent Steering Committee of the trial based on the review of recently published cardiovascular outcome trials (and 3-point MACE removed from key secondary endpoints). 4-point MACE became a tertiary endpoint.</li><li>-The eGFR cut off in the key secondary endpoint 'composite renal endpoint (renal death, sustained ESRD, sustained decrease of 50% or more in eGFR)' was changed to 40% in response to the National Institutes of Health (NIH) / Food and Drug Administration (FDA) scientific workshop on GFR decline as an endpoint for clinical trials in chronic kidney disease (CKD), and the current clinical landscape on decline in eGFR and subsequent risk of end stage renal disease and mortality.</li><li>- The formal confirmatory interim analysis was removed.</li><li>- The hypothesis testing was changed, with a higher alpha-level assigned to the composite renal endpoint.</li></ul>

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported